

International Cellular Medicine Society Off Shore Stem Cell Survey Report

2nd Edition 2010



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Introduction to the 2^{nd} Edition

The <u>International Cellular Medicine Society</u> is a professional medical nonprofit association dedicated to the advancement of safe and effective stem cell therapies through education and peer oversight. Representing physicians and researchers from over 20 countries and on six continents, the ICMS is guided by volunteer <u>Governing and Advisory Boards</u> that publish best practice <u>Standards and Guidelines</u> for the collection, culturing and re-implantation of adult stem cells and provide oversight to a robust <u>Treatment Registry</u> of patient reported long term outcomes and complications tracking data from cell based medical treatments.

As part of its educational mandate, the ICMS publishes an annual Off Shore Stem Cell Clinic Survey Report to provide an apples-to-apples comparison of stem cells clinics across the world. The scope of the work is to compile a wide range of data, from cell source to procedure cost, that are critical to the evaluation of any treatment, and to present this data in an unbiased and comparative fashion. With 22 participating clinics from 13 countries, the 2nd Edition of this report is an ambitious, important and unparalleled survey. It is not, however, a complete survey. The data in this report is primarily collected by patients doing interviews with clinics. While this has been useful in teasing out important information about basic treatment procedures, it does not provide a complete view of the clinical or medical processes of the surveyed clinics. While we acknowledge the value of compiling data from clinical trials as an evaluative model, we choose to approach this report from an observational methodology in hopes of achieving a broader base of participation and a higher level of transparency. Our approach has been, from the beginning, to create an evolving survey report that would illuminate the stem cell treatment landscape from the patient's perspective.

To accomplish this goal, we have made significant modifications from the original Off Shore Stem Cell Clinic Report published in 2009. Aside from more than doubling the number of clinics evaluated, provided a chart of treatments offered and developed levels for the evaluation for the complexity of the processing and implantation of stem cells. Combined, this collection of data serves to provide an even greater insight into the treatments options offered at each clinic.

Additionally, the we have identified those clinics that participate in the <u>ICMS Open Treatment</u> <u>Registry</u>. These clinics have agreed to allow the ICMS to provide long term follow up and tracking to monitor patient well being and report on treatment efficacy. Combined, these new levels of information give a far greater insight into the practices of these treatment centers.

This report also provides two unique perspectives on the importance of the evaluation of stem cells clinics: Barbara Hanson, the founder of <u>Stem Cell Pioneers Forum</u> writes of her experiences as a stem cell patient and Dr Christopher J Centeno, MD, the medical director of the ICMS and a pioneer in the field of stem cells therapies, leverages his experience and insights to speak on Vetting Stem Cell Clinics. These pieces provide both medical and personal bookends to define the importance of this report for patients and physicians.

David Audley Executive Director, ICMS



Review of Participating Clinics



Stem Cell Implantation Levels



Stem Cell Process Levels





Review of Participating Clinics

Clinic	Country	Patients treated	Cell Type/ Classification/ Source	Procedure cost in US\$	ICMS registry	Implant ation Level	Processing Level	Website
CancunClinic	Mexico	DND	Autologous/HSC/ BM	DND	No	1	N/A	www.cancunstemcellclinic.com
EmCell	Ukraine	5,000	Allogeneic/Embryonic/ Fetal tissue	DND	No	1	N/A	www.emcell.com
Hongtianji Neuroscience Academy	China	DND	Allogeneic / Embryonic / Fetal Olfactory Bulb	22,000	No	1	3	www.nrrfr.com
Instituto Brazzini Radiologos	Peru	>100	Autologous/BMAC/BM	10,000- 15,000	Yes	3	1	www.brazzini.com.pe
Instituo de Medicina Regenerativa	El Salvadore	200	Autologous/HSC/BM	12,000- 35,000	No	1	2	www.fvina.org
Internation Stem Cell Institute	Costa Rica	2000	Allogeneic/HSC/ placenta	9,500	No	1	1	www.istemcelli.com
Maison De Sante	Peru	800	Autologous/ HSC CD34+/BM	6,000	Yes	2	3	www.maisondesante.org.pe
Miplant Clinic	Korea	<50	Autologous/MSC/ Adipose tissue	6,500	Yes	2	1	N/A
Nepsis Institute	Mexico	900	Autologous/MSC/BM	15,000- 25,000	No	1,2	N/A	www.nepsisinstitute.com
Norbet Sass	Germany	600	Autologous/MSC/BM	DND	No	1	1	www.infoadultstemcell.com
Regencell	Thailand, Mexico, India	DND	Allogeneic/HSC/ Cord blood	DND	No	N/A	3	www.regenecell.com
Regenerative Medicine Institute	Mexico	<10	Autologous/HSC/BM	25,000	Yes	3	3	www.regenerativemedicine.mx
Regenebody	Dominican Republic	DND	Autologous/HSC/ Adipose tissue	DND	No	N/A	N/A	www.regenobody.com
Regenocyte	Dominican Republic	DND	Autologous/HSC/ Peripheral blood	65,000	No	2	N/A	www.regenocyte.com
Rejuvenare	Dominican Republic	>800	Autologous/MSC/BM	35,000	No	2	1	www.rejuvenare.com
Servicio de Investigaciones en Medicina Regenrativa	Argentina	<50	Autologous/MSC/BM	15,000	Yes	2	1	N/A
Stem Cell Biotherapy	Peru	200	Allogeneic/HSC/ Umbilical cord blood	25,000	No	N/A	1	www.stemcellbiotherapy.com
StemCell RegenMed	Peru	500	Autologous/MSC/BM or peripheral blood	10,000- 25.000	No	1	3	www.stemcellregenmed.com
TheraVitae	Thailand	350	Autologous/HSC/ Peripheral bood aphaeresis	45,000	No	2	3	www.theravitae.com
Tiantan Puhua Stem Cell Clinic	China	DND	Autologous/HSC/BM	32,000	No	2	3	www.stemcellspuhua.com
Wendeng Orthopedics Hospital	China	<10	Autologous/MSC/BM	4,500	Yes	3	3	www.chinawdzg.com
Xcell Center	Germany	2000	Autologous/MSC/BM	10,000- 15,000	No	3	N/A	www.xcell-center.com
Abbreviations:				Stem cell in levels:	plantatio	on		

DND: did not disclose N/A: non available/unable to verify HSC: Hematopoietic stem cell MSC: Mesenchymal stem cell BMAC: Bone marrow aspirate concentrate Level 1: Intravenous injection Level 2: Local injection without imaging guidance

Level 3: Local injection with imaging guidance

Stem cell processing levels:

BM: Bone Marrow

- Level 1: Centrifugation/concentration of the original sample without purification/processing of the stem cells
- Level 2: Stem cell isolated from the original sample but no or minimal processing
- Level 3: Use of advanced cell culture techniques to expand the stem cell numbers for yield

Open Treatment Registry

The ICMS <u>Treatment Registry</u> is a unique database built to capture patient reported data on outcomes and potential complications from stem cell treatments. By following patients for 20 years after their procedures, the ICMS provides long term reporting and evidence for the safety and efficacy of these promising therapies. The goal of the ICMS Treatment Registry is to bring a level of transparency and peer oversight to clinics worldwide.

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	Kecreebon 1	
	Sitting :	
	Headaches :	
	Work :	
	Frequency of Pain :	
	Lifting 1	
	Walking :	
	Standing :	
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The ICMS provides two separate Treatment Registries. The Open Treatment Registry is open to any stem cell clinic that is willing to engage with the ICMS to provide comprehensive patient tracking. The ICMS Certified Treatment Registry is open only to those clinics which have been granted ICMS Accreditation through the certification of the clinical and laboratory practices of the clinic in accordance with the published Guidelines of the ICMS.

Data within the Registry is tracked by the ICMS through pro-active communications with patients on a scheduled basis. Patients are asked a series of objective and observational questions based upon their specific procedure and a

standard complications questionnaire. Any potential complaint raised by the patient is reviewed by the medical staff and volunteers of the ICMS. Complaints are immediately reported back to the treating physician who is required to follow up with the patient and establish whether the complaint may or may not be a by-product of the stem cell procedure. All complaints must be adjudicated and the resolution is reported back to the ICMS to be tracked in the Treatment Registry.



Open Treatment Registry continued

Data within the Treatment Registry is tracked on a variety of levels from cell lines (meaning the specific stem cells that are registered with the ICMS used by a single clinic) to procedures to provide as clear and as complete a record of safety s possible. While participating clinics within the Treatment Registry determine the access to their own procedure data, the ICMS closely monitors the outcomes and complications reporting and reserves the right to publicly evaluate the efficacy and safety of any cell line, procedure or clinic according to the collected data.

Participating clinics are able to set access levels to their

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procedure data collected in the Treatment Registry. This allows a clinic to share outcomes and complications data with either the general public through the ICMS, with researchers or with other physicians. This will allow clinics with positive results to evidence the value of their specific treatment to patients or physicians searching for healthcare options.

All confidential patient data is kept private and secure according to applicable local and international laws including, but not limited to the Health Insurance Portability and Accessibility Act of 1996 (<u>HIPAA</u>).

Clinics and physicians who wish to participate in the Treatment Registry should contact the ICMS at <u>info@cellmedicinesociety.org</u>.



Clinic Comparisons By participation in the Open Treatment Registry.

Clinic	Stem Cells Source	Procedure Cost	Registry Participant
Norbet Sass	Autologous	Did not disclose	No
EmCell	Allogeneic	Did not disclose	No
Hongtianji Neuroscience Academy	Autologous	\$22,000	No
Instituto Brazzini Radiologos	Autologous	\$10,000 - \$15,000	Yes
Instituto de Medicina			
Regenerativa	Autologous	\$12,000 - \$35,000	No
International Stem Cell Institute	Autologous	\$9,500	No
Maison De Sante	Autologous	\$6,000	Yes
Miplant	Autologous	\$6,500	Yes
Nepsis Institute	Autologous	\$15,000 - \$25,000	No
Regencell	Autologous	Did not disclose	No
Regenerative Medicine Institute	Autologous	\$8,000 - \$30,000	Yes
Regenobody	Allogeneic	Did not disclose	No
Regenocyte	Allogeneic	\$35,000	No
Rejuvenare	Autologous	\$35,000	No
Servicio de Investigaciones en			
Medicina Regenerativa –			
Sanatorio UOCRA	Autologous	\$15,000	Yes
Stem Cell Biotherapy	Allogeneic	\$25,000	No
StemCell RegenMed	Autologous	\$10,000 - \$25,000	No
TheraVitae	Autologous	\$45,000	No
Tiantan Puhua Stem Cell Clinic	Autologous	\$32,000	No
Wendeng Orthopedics Hospital	Autologous	\$4,500	Yes
XCell Center	Autologous	\$10,000 - \$15,000	No





Methodology

The ICMS Off Shore Stem Cell Clinic Survey has been created to provide a compilation of clinical, procedural and therapeutic data. Our objective is to provide an unbiased and objective survey of clinics advertising stem cell therapies. These assessments and evaluations will help patients and physicians navigate an increasingly expensive and competitive practice area, and to help patients make informed health-care decisions.

The clinics evaluated were gathered from online advertising and key-word searches, postings from online forums and submissions from current, former and prospective stem cell therapy patients. All clinics were contacted by patients requesting information about stem cell therapies for a variety of ailments, ranging from congestive heart failure to Parkinson's Disease.

The clinics were approached by prospective patients who made a simple inquiry by either email or through a contact form on the clinic's website. Upon receipt of a response from the clinic's staff, patients replied with a short list of questions developed by the ICMS to provide insight into the processes and procedures for the harvesting, culturing and implantation of the stem cells.

The data collected from the patients has been reviewed by medical professionals from the ICMS.



Disclaimer: The ICMS makes no warranties about the information contained within this report. The information provided in this report does not constitute medical advice and is not intended by either the authors or by the ICMS to do so. Patients and physicians should not rely on any material in this report to make or refrain from any medical decision or action. Evaluated clinics are welcome to submit additional or amended data to the ICMS to for re-examination. It is the position of the ICMS that patients should make informed decisions and consult with a medical professional when evaluating any medical procedure. The ICMS cannot be held responsible for any misreported information. All material within the Off Shore Stem Cell Clinic Report is assumed to be factually correct and respectful of all copyright laws. Any errors or omissions should be brought to the attention of the ICMS.



Conditions Treated Participating Stem Cell Clinics

The information presented in the following pages has been gathered by the ICMS from the participating stem cells clinics. The information is presented for educational purposes, and not intended to imply the safety or efficacy of any procedure. The data is presented for comparative purposes only. The ICMS does not provide medical advice, diagnosis or treatment. The Content is not intended to be a substitute for professional medical advice, diagnosis, or treatment. Always seek the advice of your physician or other qualified health provider with any questions you may have regarding a medical condition. Never disregard professional medical advice or delay in seeking it because of something you have read in this report. Any errors or omissions should be brought to the attention of the ICMS.







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Conditions Treated

Condition	Clinics Offering Treatment
Acute Myocardial Infarcton	Rejuvenare
AIDS	EmCell
$\mathbf{A}_{\mathbf{r}}$	Regenobody, Regencell, EmCell, Hongtianji
Amyotrophic lateral scierosis (ALS)	Neuroscience Academy, Stem Cell Biotherapy
	Regenerative Medicine Institute, Regenobody, Regencell,
Alzneimer's disease	Stem Cell Biotherapy, EmCell
Amiotrophic Lateral Disease	Instituto de Medicina Regenerativa
Anemia	International Stem Cell Institute, EmCell
Anterior Spinal Artery Syndrome	Hongtianji Neuroscience Academy
Anti-aging	International Stem Cell Institute, EmCell
Arterial Hypertension	EmCell
Arthritis	Regenobody
A	Regenerative Medicine Institute, StemCell RegenMed,
Autism	Regencell, Stem Cell Biotherapy
Auto-immune diseases	Regenobody, International Stem Cell Institute
Bone non-union	Wendeng Orthopedics Hospital
Brain damage	StemCell RegenMed
Brain Trauma	Hongtianji Neuroscience Academy
Brochiectasis	Nepsis
Bulging disc	Wendeng Orthopedics Hospital
	Regenerative Medicine Institute, Stem Cell Biotherapy,
Cancer	EmCell
Cordiaa Diagoaa	Regenobody, Regencell, International Stem Cell Institute,
Calulac Disease	Stem Cell Biotherapy, Regenocyte
Cardio-myopathy	TheraVitae, Rejuvenare
Cerebellar Ataxia	Regencell
Cerebral hypoxia	Instituto Brazzini Radiologos
	StemCell RegenMed, Regencell, Stem Cell Biotherapy,
Cerebral Palsy	Tiantan Puhua Hospital, Hongtianji, Neuroscience
	Academy, Nepsis
Cirrhogic	Instituto Brazzini Radiologos, Norbett Sass, Rejuvenare,
CITTIOSIS	Maison de Sante Clinic
Congestive Heart Failure	TheraVitae, Instituto de Medicina Regenerativa,
	Rejuvenare
	Regenerative Medicine Institute, StemCell RegenMed,
	Regencell, Rejuvenare, Stem Cell Biotherapy
Coronary artery disease	TheraVitae
Coronary or Non-Coronary	Instituto de Medicina Regenerativa
Cardiomiopaty	
Critical limb ischemia	Servicio de Investigaciones en Medicina Regenerativa
Crohn's Disease	Regencell, Instituto de Medicina Regenerativa, EmCell, Stem Cell Biotherapy



Conditions Treated

Condition	Clinics offering Treatment
Cronic Trombo Embolic Pulmonary Hypertension	Instituto de Medicina Regenerativa
Demetia	Hongtianji Neuroscience Academy, Regenocyte Instituto Brazzini Radiologos, Servicio de Investigaciones en Medicina Regenerativa, Regenerative Medicine Institute, Norbett Sass, Stem Cell Biotherapy, Maison de Sante Clinic, EmCell, Instituto de Medicina Regenerativa, Regencell, Xcell Center, Regenobody, StemCell
Emphysoma	Regenimed
Eye-useases	Mondong Orthonodice Hospital
Feiliolai fiedu avasculai fiaicosis	Vendeng Onnopedics Hospital
	Nepsis Regenerated Veal Center Regeneral Rejuvenare
Heart Disease	Negenobody, Aceli Center, Negencell, Nejuvenare,
Hereditary Spactic Paraparesis	Hongtianii Neuroscience Academy
Inflammatory Rowel Disease	
Inflammatory Dower Disease	Keyencen
Cardiomyopathy	Instituto de Medicina Regenerativa, Rejuvenare
loint cartilage ligament tendon injur	V
and/or degeneration	^y Wendeng Orthopedics Hospital
Kidney Disease	Regenology Regencell Stem Cell Biotherapy Nepsis
Leukemia	Regenerative Medicine Institute
Liver Disease	Regencell
	Regenerative Medicine Institute Regencell
Macular Degeneration	Regenerative Medicine Institute, Regencell, Instituto de Medicina Regenerativa
Multiple Sclerosis	Instituto Brazzini Radiologos, Cancun Clinic, Hongtianji Neuroscience Academy, Instituto de Medicina Regenerativa, EmCell, Norbett Sass, StemCell RegenMed, Regencell, Regenobody, Stem Cell Biotherapy
Muscular Distrophy	Regenobody, Regencell, Instituto de Medicina Regenerativa, Stem Cell Biotherapy, EmCell
Myelits	Hongtianji Neuroscience Academy
Myocardial infarction	Servicio de Investigaciones en Medicina Regenerativa
Neuro AxonalDystrophy	Hongtianji Neuroscience Academy
Neurodegenerative Diseases	Tiantan Puhua Hospital, International Stem Cell Institute, Nepsis
Neurological diseases	Xcell Center,
Neuropathy	Instituto de Medicina Regenerativa
Orthopedics	Xcell Center, Miplant, Wendeng Orthopedics Hospital



Conditions Treated

Condition	Clinics Offering Treatment
Parkinson's Disease	Instituto Brazzini Radiologos, Maison de Sante Clinic, Regenerative Medicine Institute, Rejuvenare, EmCell, Instituto de Medicina Regenerativa, Regencell, Regenobody, StemCell RegenMed, Norbett Sass, Stem Cell Biotherapy
Peripheral and Central Vascular Deficiency	Regenerative Medicine Institute
Peripheral Arteripathy	Instituto de Medicina Regenerativa
Peripheral Artery Disease (PAD)	Instituto Brazzini Radiologos, Regenobody
Peripheral circulation	Regenocyte
Primary Lateral Sclerosis (PLS)	Regencell, Stem Cell Biotherapy
Pulmonary disease	Regenocyte
Pulmonary Emphysema	Instituto de Medicina Regenerativa, Rejuvenare, Maison de Sante Clinic
Pulmonary Fibrosis	Instituto de Medicina Regenerativa
Refractory angina	Maison de Sante Clinic
Renal insufficiency	Regenocyte
Rheumatoid Arthritis	Regenerative Medicine Institute, Regenobody, Regencell, EmCell, Stem Cell Biotherapy
Scleroderma	StemCell RegenMed, Regencell,
Severe heart disease	StemCell RegenMed
Spinal Cord Injuries	Regencell, Tiantan Puhua Hospital, Hongtianji Neuroscience Academy, Rejuvenare, Stem Cell Biotherapy, Nepsis
Spinal Macular Athrophy	Hongtianji Neuroscience Academy
Stroke	Instituto Brazzini Radiologos, Regenobody, Regencell, Instituto de Medicina Regenerativa, Stem Cell Biotherapy
Terminal Heart Failure	Maison de Sante Clinic
Transverse Myelitis	Regenobody, Regencell





Patient Voices:

I am co-founder of the Stem Cell Pioneers forum. Almost three years ago, I had my first stem cell therapy at a clinic in Mexico. I have a terminal lung disease and being desperately ill, one does desperate things.

After becoming extremely ill after the treatment (I went to the clinic with another lady that I had met online with the same condition who also fell ill), we both decided that we needed some way to connect with others to discuss stem cell therapy and lend support to those thinking of having treatment and those that had already had it. No such forum existed that was moderated solely by patients.

It has been almost three years since the forum was founded and many patients still must seek treatment offshore. Not until the ICMS published the Off Shore Stem Cell Clinic Report has there been a way for patients to evaluate clinics in a way that removes any type of sales hype from the picture. Our forum appreciates this valuable information for our members. It helps them assess the clinics that they are considering and lets them make a more informed decision than what is available to them on company websites and from medical tourism brokers.

Our mission on the Stem Cell Pioneers forum is to keep our members informed so that they won't go through what we did when we went for our first therapy, totally uninformed. Thanks to ICMS for the Off Shore Stem Cell Clinic Report our mission is being achieved.

Barbara Hanson Co-Founder Stem Cell Pioneers <u>www.stemcellpioneers.com</u>



Overview of the Processing of Stem Cells

Level 1 Stem Cell Procedure - Centrifugation

A level 1 treatment is the most basic form of stem cell therapy. It is defined as a basic centrifuge concentration procedure that doesn't produce isolated stem cells, but a mixture of cells, a few of which are stem cells. In these treatments, the stem cells are not exposed to growth factors and are not culture expanded. An example of a Level 1Treatment is a bone marrow aspirate concentrate (BMAC) to treat diabetes where the nucleated cells are centrifuged and then re-implanted into the patient via intravenous delivery.

Level 2 Stem Cell Procedure - Minimal Processing

A Level 2 treatment is defined as one in which the stem cells are isolated, but there is no or minimal expansion of the cells in a lab (the goal of processing is not cell expansion for yield). These stem cell preps are generally conditioned with various growth factors to activate or differentiate cells. Examples of Level 2 Treatment would be Platelet Rich Plasma (PRP) combined with a medication or growth factor, or a specific mixture of proprietary cell types that are prepared in a bedside machine. Another example would be hematopoietic stem cells that are conditioned for several days using a specific growth factor.

Level 3 Stem Cell Procedure - Culture Expansion

A Level 3 Treatment is the most complex and advanced approach to stem cell therapy. This treatment level is defined by the use of advanced cell culture techniques to expand cell numbers for yield. This procedure requires the use of a laboratory to culture cells. An example of a Level 3 Treatment would be culture expanded mesenchymal stem cells.









Overview of Implantation Procedures Explanation of Treatment Levels



Level 1 – Basic Injection

This is the most basic and least complicated of injection methods. The most common basic injection procedures is the intravenous injection of adult stem cells means that many of the cells may end up in the lungs, not other tissues. This is called a "pulmonary first pass" effect.



Level 2 – Intermediate Injection

This intermediate injection requires expertise and utilizes a specific placement of the stem cells within the patients without imaging guidance. An example would be intra-articular injection where the stem cells might be directly injected into the cavity of a joint.



Level 3 – Advanced Injection

This advanced process requires specific placement of the stem cells through the use of imaging guidance. This process is the most technically challenging, requiring a medical specialist with a high level of expertise and interventional experience to deliver cells. An example would be intra-articular placement with fluoroscopy or intra-arterial placement with fluoroscopy.



Clinic Comparisons: By complexity of stem cell processing and implantation.

Clinic	Stem Cells Used	Stem Cell Process Complexity Level	Implantation Complexity Level	Procedure Cost
EmCell	Allogeneic	Unable to Verify	Level 1	Did not disclose
Hongtianji Neuroscience Academy	Allogeneic	Level 3	Level 1	\$22,000.00
Instituto Brazzini Radiologos	Autologous	Level 1	Level 3	\$10,000.00
Instituto de Medicina Regenerativa	Autologous	Level 3	Level 1	\$12,000 - \$35,000
International Stem Cell Institute	Allogeneic	Level 1	Level 1	\$9,500.00
Maison De Sante	Autologous	Level 1	Level 2	\$6,000.00
Miplant Clinic	Autologous	Level 1	Level 2	\$6,500.00
Nepsis Institute	Autologous	Unable to Verify	Level 1,2	\$15,000 - \$25,000
Norbet Sass	Autologous	Level 1	Level1	Did not disclose
Regencell	Allogeneic	Level 3	Unable to verify	Did not disclose
Regenerative Medicine Institute	Autologous	Level 3	Level3	\$8,000 - \$30,000
Regenobody	Autologous	Unable to Verify	Unable to verify	Unable to Verify
Regenocyte	Autologous	Unable to Verify	Level 2	\$65,000.00
Rejuvenare	Autologous	Level 1	Level 2	\$35,000.00
Servicio de Investigaciones en Medicina Regenerativa – Sanatorio UOCRA	Autologous	Level 1	Level 2	\$15,000.00
Stem Cell Biotherapy	Allogeneic	Level 1	Unable to verify	\$25,000.00
StemCell RegenMed	Autologous	Level 3	Level 1	\$10,000 - \$25,000
TheraVitae	Autologous	Level 3	Level 2	\$45,000.00
Tiantan Puhua Stem Cell Clinic	Autologous	Level 3	Level 2	\$32,000.00
Wendeng Orthopedics Hospital	Autologous	Level 3	Level 3	\$4,500.00
XCell Center	Autologous	Unable to Verify	Level 3	\$10,000 - \$15,000



Vetting Stem Cell Therapies

By Christopher J. Centeno, MD Medical Director, International Cellular Medicine Society

Internet advertisements for stem cell therapies abound. It seems like every disease imaginable has an advertised cure. It is incredibly difficult for patients and physicians alike to vet these therapies. After many years of clinical experience in collecting, lab processing, and deployment of adult stem cells, I've developed a series of questions I use with my patients.

Treating Everything- The development of treatment protocols for stem cells is difficult and is disease and tissue specific. This means that valid treatment isn't as easy as sprinkling magic stem cells on the patient. For example, the treatment protocol for knee osteoarthritis has a completely different approach than cardiac disease. Ideal stem cell clinics are those that are operating with a concentrated focus on a small collection of diseases and have perfected their protocols for those diseases. So if the clinic advertises that it treats everything from ALS to Parkinson's to knee arthritis, this usually Indicates that it's not operating at a high level of credibility.

Cell Source Matters- Where are the stem cells obtained? Are they from the same patient (autologous) or from an allogeneic source? Manv experts in the stem cell industry agree that autologous cells are more likely to have a much more robust safety profile than cells obtained from a donor. In particular, genes of the donor remain active in the host (which could have either a potentially positive or negative impact). In addition, knowing the degree of rigor with which donor cells are screened for communicable disease is obviously important. Having said that, if the patient has a disease that results in a likely defect of stem cell function and is severely disabled, allogeneic stem cells may be considered in the risk vs. benefit equation.





Vetting Stem Cell Therapies , cont.

By Christopher J. Centeno, MD Medical Director, International Cellular Medicine Society

Cell Type Matters- Embryonic and fetal stem cells have been documented to have a higher risk of tumor formation (teratoma) as well as the allogeneic risks discussed above. Cord blood cells are likely also more risky for the While these cell types might be same reasons. appropriate to use in patients who have life threatening illnesses or who have no quality of life, the risk/benefit ratio is not appropriate to use them for routine disease applications. As an alternative, adult stem cells are present in all of us and have been shown to be effective in animal and early human clinical models for treating a wide variety of diseases. These cells can be broken into two commonly used: main types that are CD34+ hematopoietic cells (HPC's) and MSC's (mesenchymal stem cells). CD34+ cells or HPC's show real promise in treating vascular and cardiac illnesses such as peripheral vascular disease and cardiac disease. MSC's show promise in many areas, including orthopedics and neurologic diseases.

Processing Matters- How the cells are processed is very important. At the most simple level, cells can be obtained from a bone marrow aspirate and spun down in a centrifuge to isolate the buffy coat (rich in nucleated cells). Most stem cell clinics in operation around the world use this simple technique, which isn't truly a "stem cell" therapy as only 1 in 100 of these cells are HPC's and 1 in 10,000-100,000 are MSC's. Even though the stem cell yields are very low, this resulting mixture (known as BMAC-Bone Marrow Aspirate Concentrate), has shown positive results in treating type II diabetes (when properly applied-see below) and in some cardiac applications. The next level of processing is cell pre-conditioning. This usually involves isolating cells as above and then applying certain growth factors in short duration incubation (a few hours to a few days at most). Finally, the most advanced type of cell processing is culture expansion, where cells are grown to higher numbers over a few weeks. Most of the animal research showing dramatic results from adult stem cell therapy use culture expansion. Few clinics take the time or have the expertise to culture expand cells, which is the Gold standard for stem cell therapy.



Vetting Stem Cell Therapies , cont.

By Christopher J. Centeno, MD Medical Director, International Cellular Medicine Society

Delivery Matters- Likely the easiest way to separate the wheat from the chafe in stem cell therapy is asking how the clinic plans on delivering cells. While IV delivery is attractive because of the low level of expertise and expense it takes to deliver cells, studies have consistently shown that adult stem cells delivered in this fashion are trapped in the lungs (pulmonary first pass effect). Of even more concern is a recent study showing that for patients considering the use of stem cells to treat CNS disorders, only about 1 in 200,000 cells injected via an IV route reaches the CNS (1.5-3.7% made it past the lungs, 0.295%) made it to the carotid artery, and 0.0005% made it past the blood brain barrier into the CNS). At this point, until these pulmonary first pass issues are worked out, credible stem cell delivery is local. This means placing cells directly into the tissue or into the arterial circulation that directly supplies the tissue. In addition, for orthopedic applications (and likely for others), it's hyper-local, meaning that placement of cells into one part of the joint may provide results; where as non-specific placement in the joint The same holds true for cardiac provides no results. placement. Placement in the cardiac arterial circulation will get some cells to the site, placement generally in the muscle will get more cells to the site, and placement in the transitional zone between the oxygenated muscle and the necrotic zone (transitional zone) will guarantee better cell survival and more cells that are capable of repair.

In summary, some simple questions can help you vet stem cell clinics. If the clinic won't answer these questions, then my advice would be to look elsewhere.

Dr. Centeno is a stem cell expert and founding member of the International Cellular Medicine Society. He practices image guided, percutaneous, orthopedic stem cell therapy in Denver, Colorado, where he maintains a state of the art stem cell culture expansion facility as part of his medical practice. He can be reached at <u>entenooffice@centenoclinic.com</u>.





Survey Results Clinical Practices of Off Shore Stem Cell Clinics

The information gathered in this survey are the results of prospective patient interactions with the clinics. In many cases, patients were unable to speak with any medical or scientific staff of the clinic. Every effort has been made to verify the data contains within this report. The "Notes" section at the bottom of clinic reports contains assertion from the clinic. These statements have not been verified by the ICMS and are included as information only. Any errors or omissions should be brought to the attention of the <u>ICMS</u>.







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Clinic Name: Hongtianji Neuroscience Academy Location: Beijing, China Primary Physician: Dr. Huang Hongyun Website: <u>www.nrrfr.com</u> Patients Treated: Did not disclose Cost per procedure: \$22,000

Overview of procedure:

Level 3 procedure that utilizes allogeneic, fetal tissue derived (embryonic) stem cells that are implanted via Level 2 injection process.

Conditions Treated:

ALS, Spinal cord injuries, Multiple Sclerosis, Brain Trauma, Cerebral Palsy, Myelitis, Neuro Axonal Dystrophy, Spinal Macular Athrophy, Anterior Spinal Artery Syndrome, Demetia Hereditary Spastic Paraparesis Freidrich's Ataxia.

Cell Type: Allogeneic Cell Classification: Embryonic Cell Source: Fetal Olfactory Bulb Tissue

How are cells isolated? Did not disclose. How are cells processed? Cells are incubated. Are cells cultured? Yes. How long are cells cultured? 3 to 10 days. Are cells exposed to growth factors? Did not disclose

How are cells re-implanted? Direct tissue injection or transplantation surgery into corona radiate. What are cells mixed with for re-implantation? Did not disclose. Does the clinic provide post-procedure follow-up? Did not disclose. How often? Did not disclose.

Notes

CMS

The clinic provides the following statement: "In order to reduce immune reaction, the clinic performs a test named cell HLAmatching is done before surgery. The procedure involves the injection of roughly 100 µliters containing about 2,000,000 OECs and 100 µliters of 2,000,000 NSCs into the bilateral corona radiate of frontal lobe of the patient's brain. " Clinic Name: Instituto Brazzini Radiologos * Location: Lima, Peru Primary Physician: Augusto Brazzini, MD ** Website: <u>www.brazzini.com.pe</u> Patients Treated: 100 Cost per procedure: \$10,000 - \$15,000

Overview of procedure:

Level 1 procedure that utilizes autologous, bone marrow derived stem cells that are re-implanted via a Level 3 injection process.

Conditions Treated:

Parkinson's disease, Cerebral hypoxia, Stroke, Multiple Sclerosis, Peripheral Artery Disease (PAD), Type II Diabetes, Cirrhosis.

Cell Type: Autologous Cell Classification: Mesenchymal Cell Source: Bone Marrow

How are cells isolated? Centrifuge How are cells processed? No isolation. Whole mononuclear portion Are cells cultured? No How long are cells cultured? Not cultured Are cells exposed to growth factors? No.

How are cells re-implanted? Intra-arterial selective catheter using fluoroscopy for guidance. What are cells mixed with for re-implantation? Saline Does the clinic provide post-procedure follow-up? Yes. How often? Follow up s provided by the ICMS in accordance with the Re-Implantation Guidelines.

* The Instituto Brazzini Radiologos is a participant in the ICMS Open Treatment Registry which provides long-term patient outcome and complications tracking. ** Dr Augusto Brazzini is a member of the ICMS and serves on several ICMS advisory boards.



MICMS

Clinic Name: Regenerative Medicine Institute * Location: Tijuana, Mexico Primary Physician: Dr. Julio E. Selva, MD Website: <u>www.regenerativemedicine.mx</u> Patients Treated: Less than 10 Cost per procedure: \$8,000 - \$30,000

Overview of procedure:

Level 3 procedure that utilizes autologous, bone marrow derived stem cells that are re-implanted via a Level 3 injection process.

Conditions Treated:

COPD, Alzheimer's Disease, Parkinson's disease, Leukemia, solid tumor cancer, Multiple Sclerosis, Type I & II Diabetes, Autism, Peripheral and Central Vascular Deficiency, Rheumatoid Arthritis, Lups and Macular Degeneration

Cell Type: Autologous Cell Classification: Hematopoietic Cell Source: Bone Marrow

How are cells isolated? Buffy coat is isolated through centrifuge How are cells processed? No answer. Are cells cultured? Yes. How long are cells cultured? 3-10 days Are cells exposed to growth factors? Yes. Cells are cultured with PRMI 1640 and supplemented with fetal bovine serum

How are cells re-implanted? Guided cardiac, pancreatic and carotid artery placement What are cells mixed with for re-implantation? Cells are rinsed with PBS Does the clinic provide post-procedure follow-up? Yes. How often? 30, 60, 90, 180 days and then annually thereafter.

* The Regenerative Medicine Institute is a participant in the ICMS Open Treatment Registry which provides long-term patient outcome and complications tracking. **C**ICMS

Clinic Name: Wendeng Orthopedics Hospital * Location: Wendeng, Shandong, China Primary Physician: Dr. Huang, Xiangjie, Dr. Jiang, Hongjiang Website: <u>www.chinawdzg.com</u> Patients Treated: Less than 10 Cost per procedure: \$4,500

Overview of procedure:

Level 3 procedure that utilizes autologous, bone marrow derived stem cells that are re-implanted via a Level 3 injection process.

Conditions Treated:

Bone non-union, joint cartilage, ligament, or tendon injury and/or degeneration, femoral head avascular narcosis and bulging disc

Cell Type: Autologous Cell Classification: Mesenchymal Cell Source: Bone marrow

How are cells isolated? Physical property of adhesion to plastic surface How are cells processed? Autologous platelet rich plasma is activated to produce growth.

Are cells cultured? Yes, with platelet lysate (PL) How long are cells cultured? Less than 21 days Are cells exposed to growth factors? No

How are cells re-implanted? Direct cell placement via needle or surgery with use of x-ray guided placement

What are cells mixed with for re-implantation? Platelet rich plasma (PRP)

Does the clinic provide post-procedure follow-up? Yes. The clinic adhere to the ICMS guidelines and participate in the ICMS registry How often? Follow up is provided by the ICMS according to the guidelines set forth in the ICMS Re-Implantation Registry Guidelines

* Wendeng Orthopedics Hospital is a participant in the ICMS Open Treatment Registry which provides long-term patient outcome and complications tracking.



Clinic Name: Norbett Sass Location: Germany Primary Physician: Norbett Sass Website: <u>www.infoadultstemcell.com/</u> Patients Treated: 600 Cost per procedure: Did not disclose

Overview of procedure: Level 1 procedure that utilizes autologous, bone marrow derived stem cells that are re-implanted via a Level 1 injection process.

Conditions Treated:

Parkinson's disease, Multiple Sclerosis, Diabetes, Cirrhosis Cell Type: Autologous Cell Classification: Mesenchymal Cell Source: Bone Marrow

How are cells isolated? By Ficol Gradient How are cells processed? Cell are incubated. Are cells cultured? No. How long are cells cultured? None. Are cells exposed to growth factors? Did not disclose.

How are cells re-implanted? Intravenous delivery. What are cells mixed with for re-implantation? Saline. Does the clinic provide post-procedure follow-up? Did not disclose. How often? Did not disclose.

Notes

The clinic posts the following statement on it website: "Cells are harvested from the hip of patients. Patients are given a "unique and specific food supplement" in advance of procedure which aid in the production of cells. Clinic asserts that these supplements are proprietary, and attests that supplements are all natural and have no harmful effects on the patient. Clinic further attests that while a patient without supplements will give 2MM stem cells per mL, post supplement ingestion patients provide 5–6MM per mL. Patients follow this schedule: Arrival on Monday for the pre-op processing. Stem cells are cells harvested on Tuesday, isolated and separated out from other cells through Ficol harvest, and re-implanted on Thursday. Post procedure, patients are asked to remain perfectly still on Friday prior to release to avoid the complication of severe migraine. "



Clinic Name: StemCell RegenMed Location: Concebir Hospital, Lima, Peru Primary Physician: Burton Feinerman, MD; Javiar Paino, MD, PhD Website: <u>www.stemcellregenmed.com</u> Patients Treated: 500 Cost per procedure: \$10,00 - \$25,000

Overview of procedure:

Level 2 procedure that utilizes autologous stem cells derived from bone marrow or peripheral blood that are re-implanted via a Level 1 injection process.

Conditions Treated:

Alzheimer's disease, Multiple Sclerosis, Parkinson's disease, Autism, brain damage, Cerebral Palsy, severe heart disease, Diabetes, COPD, Chronic Renal disease, Scleroderma.

Cell Type: Autologous Cell Classification: Mesenchymal Cell Source: Bone marrow Peripheral blood

How are cells isolated? Using Ficol gradient How are cells processed? Via culture Are cells cultured? Yes How long are cells cultured? 1-3 days Are cells exposed to growth factors? Yes Brain derived neurotrophic factor, nerve growth factor, vascular endothelial growth factors are used

How are cells re-implanted? Direct injection What are cells mixed with for re-implantation? No answer Does the clinic provide post-procedure follow-up? No answer How often? No answer

Notes

The clinic provided the following information: "Neurodegenerative disease patient receive stem cells through injections via spinal cord and verticals of the brain. Cardiac patients receive stem cells intravenously into coronary vessels or myocardium. Diabetes patients receive stem cells intravenously or directly into the pancreas via laparoscopy. COPD patients receive stem cells intravenously and by nebulizer inhalation."



Clinic Name: Regenobody Location: Dominican Republic Primary Physician: Dr. Tonino di Giamberardino Website: <u>www.regenobody.com/</u> Patients Treated: Did not disclose. Cost per procedure: Did not disclose.

Overview of procedure: Unable to verify Procedure or Re-Implantation Level. Utilizes autologous, adipose derived stems.

Conditions Treated:

Auto Immune Disorders Multiple Sclerosis ALS ,Muscular Dystrophy Alzheimer's Disease , Parkinson's Disease Cardiac Disease Peripheral Artery Disease , Diabetes Psoriasis, Diabetes Mellitus type 2, Rheumatoid Arthritis Joint, Tendon and Arthritic Conditions Spinal Cord Injuries, Kidney Disease , Stroke, Heart Disease , Transverse Myelit.

Cell Type: Autologous Cell Classification: Hematopoietic Cell Source: Adipose (Fat)

How are cells isolated? Did not disclose. How are cells processed? Did not disclose. Are cells cultured? Did not disclose. How long are cells cultured? Did not disclose. Are cells exposed to growth factors? Did not disclose.

How are cells re-implanted? Did not disclose. What are cells mixed with for re-implantation? Did not disclose. Does the clinic provide post-procedure follow-up? Did not disclose. How often? Did not disclose.



Clinic Name: XCell Center Location: Dusseldorf & Cologne, Germany Primary Physician: Dr C. Beythien , Dr N. Haberland Website: <u>www.xcell-center.com</u> Patients Treated: 2000 Cost per procedure: \$10,000 - \$15,000

Overview of procedure: Unable to verify Procedure Level. Utilizes autologous, bone marrow derived stem cells that are reimplanted via a Level 3 injection process.

Conditions Treated:

Neurological diseases, Heart, Diabetes, orthopedics, several eye-diseases

Cell Type: Autologous Cell Classification: Mesenchymal Cell Source: Bone Marrow

How are cells isolated? Did not disclose - Classified Information How are cells processed? Via "patented method of extraction" Are cells cultured? Yes How long are cells cultured? N/A Are cells exposed to growth factors? N/A

How are cells re-implanted? Direct placement with MRI/PET/CT guided direct brain injections, catheter-based CT angiography for heart and diabetes, CT guided treatment for joints. What are cells mixed with for re-implantation? Did not disclose. Does the clinic provide post-procedure follow-up? Yes. How often? Did not disclose.

Notes

CICMS

The clinic makes the following claim "In accordance to German law and European guidelines, The XCell-Center is the first privately-owned clinic in Europe to specialize in regenerative medicine using patients' own (autologous) bone marrow stem cells. In addition offering stem cell therapy, the XCell-Center is involved in several scientific projects like; second and third generation stem cells. Second generation stem cells will enable to multiply mesenchymal cells (multiple treatment option). Third generation stem cells will allow to target specific cells (multiplied targeted progenitor cells, f.e. progenitor neurocells)." Clinic Name: Regencell Location: India, Thailand and Mexico. Primary Physician: Multiple Website: <u>www.regenecell.com</u> Patients Treated: Did not disclose. Cost per procedure: Did not disclose.

Overview of procedure: Level 3 procedure that utilizes allogeneic, cord blood derived stem cells that are implanted via an unverified injection process.

Conditions Treated:

ALS, Alzheimer's, Autism, Cardiac Disease, Cerebellar Ataxia, Cerebral Palsy, COPD, Crohn's Disease, Diabetes, Diabetes Type II, Eye Diseases, Heart Disease, Kidney Disease, Liver Disease, Lupus, Macular Degeneration, Multiple Sclerosis, Muscular Dystrophy, Parkinson's Disease, Primary Lateral Sclerosis, Rheumatoid Arthritis, Scleroderma, Spinal Cord Injuries, Stroke, Inflammatory Bowel Disease, Transverse Myelitis.

Cell Type: Allogeneic Cell Classification: Hematopoietic Cell Source: Cord blood

How are cells isolated? How are cells processed? Did not disclose. Are cells cultured? Yes. How long are cells cultured? 3+ weeks. Are cells exposed to growth factors? Did not disclose.

How are cells re-implanted? Did not disclose. What are cells mixed with for re-implantation? Did not disclose. Does the clinic provide post-procedure follow-up? Did not disclose. How often? Did not disclose.

Notes

The clinic states "To obtain sufficient numbers, cells are encouraged to multiply indefinitely in the laboratory. This process entails isolating cells from umbilical cord and growing them up in a cell culture facility where the multipotency of the cells can be expanded over several population doublings. The clinic states that their optimized culture conditions resulted in more than 50 population doublings of umbilical cord mesenchymal cells after 15 weeks. The clinic further asserts that "a clinical quantity of 100 million mesenchymal stromal cells with retained differentiation potential could be obtained from umbilical cord MSCs within approximately 7 weeks."



Clinic Name: Tiantan Puhua Hospital Location: Beijing, China Primary Physician: Did not disclose Website: <u>www.stemcellspuhua.com</u> Patients Treated: Did not disclose Cost per procedure: \$32,0000

Overview of procedure: Level 3 procedure that utilizes autologous, bone marrow derived stem cells that are re-implanted via a Level 2 injection process.

Conditions Treated:

Neurodegenerative Diseases, Cerebral Palsy, Spinal Cord Injuries.

Cell Type: Autologous Cell Classification: Hematopoietic Cell Source: Bone Marrow

How are cells isolated? Did not disclose. How are cells processed? Cells are incubated. Are cells cultured? Yes. Cell are induced into neural cells through culture. Did not disclose methods. How long are cells cultured? 3+ weeks. Are cells exposed to growth factors? Yes. Did not disclose factors.

How are cells re-implanted? Injection via lumbar puncture into cerebral spinal fluid.

What are cells mixed with for re-implantation? Did not disclose. Does the clinic provide post-procedure follow-up? Did not disclose. How often? Did not disclose.

Notes

The clinic asserts that "With its proprietary combination of medicines, these cultured stem cells can be 'awakened' and start to proliferate, differentiate and produce more brain cells. "



Clinic Name: International Stem Cell Institute Location: Neuvo Progresso, Mexico Primary Physician: Omar Gonzales, MD Website: <u>www.istemcelli.com</u> Patients Treated: 2000 Cost per procedure: \$9,500

Overview of procedure:

Level I procedure that utilizes allogeneic, placenta derived stem cells that are implanted via a Level 1 injection process.

Conditions Treated:

Anti-aging, Cancer, auto-immune diseases, cardiovascular, immunodeficiency, neurodegenerative, anemia. Cell Type: Allogeneic Cell Classification: Hematopoietic Cell Source: Placenta

How are cells isolated? Did not disclose. How are cells processed? Frozen after harvest. Are cells cultured? No. How long are cells cultured? None. Are cells exposed to growth factors? No.

How are cells re-implanted? Direct subcutaneous injection. What are cells mixed with for re-implantation? Blood. Does the clinic provide post-procedure follow-up? Did not disclose. How often? Did not disclose.

Notes

The clinic makes the following assertion: "Stem cells are harvested from placenta a week before the patient arrives. Stem cells are then frozen, and revived just prior to injection. The clinic doctor injects several hundred million stem cells into the patient. The procedure creates a bulge at the injection site, and the body slowly incorporates the cells as needed. Clinic asserts that the bulge is noticeable for 4 to 6 weeks. Clinic states that results begin to appear after 3 months, and will continue to give "strong results" for up to a year. Additionally, clinic claims that there will be minimal continued effects for up to 2 years post procedure. The procedure tends to take about 20 minutes, and the clinic claims that it is so painless 'a small child slept through it.' Clinic asserts that autologous procedures are invasive and that taking cells from a sick individual will not result in healing."



Clinic Name: TheraVitae Location: Bangkok, Thailand Primary Physician: Dr Thein Hut Website: <u>www.theravitae.com</u> Patients Treated: 350 Cost per procedure: \$45,000

Overview of procedure:

Level 3 procedure that utilizes autologous, peripheral blood derived stem cells that are re-implanted via a Level 2 injection process.

Conditions Treated:

Coronary artery disease, Cardio-myopathy and Congestive heart failure. Cell Type: Autologous Cell Classification: Hematopoietic Cell Source: Peripheral blood aphaeresis

How are cells isolated? Cells are separated by density gradient How are cells processed? Cells are incubated. Are cells cultured? Yes How long are cells cultured? 3 to 10 days Are cells exposed to growth factors? Yes. Cells are exposed to VEGF

How are cells re-implanted? Catheter implant or direct myocardial injection.

What are cells mixed with for re-implantation? Basic growth medium. Does the clinic provide post-procedure follow-up? Did not disclose. How often? Did not disclose.

Notes

According to the clinic, 75% of Theravitae patients experience substantial improvements in the quality of their lives. Among the improvements cited are: fewer breathing problems, fewer chest pains, increased mobility, less fatigue and more energy. The clinic asserts that the physicians in Bangkok, Thailand who carry out the procedures are trained in the United States, and accredited to practice in the USA. The clinic will pay up to \$2,000 towards patient doctor's airfare to Thailand, and pay for 5 nights' hotel accommodation, so that your physician is beside the patient during the adult stem cell treatment process.



Clinic Name: Rejuvenare Location: Dominican Republic and Lima, Peru. Primary Physician: Jorge Tuma, MD ** Website: <u>www.rejuvenare.com</u> Patients Treated: 800+ Cost per procedure: \$35,000

Overview of procedure:

Level 1 procedure that utilizes autologous, bone marrow derived stem cells that are re-implanted via a Level 2 injection process.

Conditions Treated:

Ischemic & Non Ischemic Dilated Cardiomyopathy, Heart Disease, Acute Myocardial Infarction, Ischemic Cardiomyopathy, Angina, Congestive Heart Failure, Diabetes, Cirrhosis, Parkinson's disease, Stroke, COPD, Pulmonary Emphysema, Spinal Cord Injury.

Cell Type: Autologous Cell Classification: Mesenchymal Cell Source: Bone Marrow

How are cells isolated? HESS Hidroxietil starch How are cells processed? Cells are centrifuged Are cells cultured? No. How long are cells cultured? No time in culture. Are cells exposed to growth factors? No

How are cells re-implanted? Endovascular Catheter What are cells mixed with for re-implantation? Saline. Does the clinic provide post-procedure follow-up? Yes. How often? Did not disclose.

** Dr Jorge Tuma is a member of the ICMS and serves on the Laboratory Advisory Board for the Society.



Clinic Name: Instituto de Medicina Regenerativa Location: San Salvador, Republic of El Salvador Primary Physician: Dr Lisandro Vazquez Sosa Website:<u>www.fvina.org</u> Patients Treated: 200 Cost per procedure: \$12,000 - \$35,000

Overview of procedure: Level 3 procedure that utilizes autologous, bone marrow derived stem cells that are re-implanted via a Level 1 injection process.

Conditions Treated:

Diabetes, COPD, Emphysema, Pulmonary Fibrosis, Idiopathic Pulmonary Fibrosis, Cronic Trombo Embolic Pulmonary Hypertension, Stroke, Multiple Sclerosis, Parkinson's Disease, Amiotrophic Lateral Disease, Primary Lateral Sclerosis, Congestive Heart Failure, Ischemic Cardiopathy, Coronary or Non-Coronary Cardiomiopaty, Peripheral Arteripathy, Muscular Distrophy, Neuropathy, Macular Degeneration, Crohn's Disease.

Cell Type: Autologous Cell Classification: Mesenchymal Cell Source: Bone Marrow

How are cells isolated? Centrifugation by gradient How are cells processed? Did not disclose Are cells cultured? Yes How long are cells cultured? 14 days Are cells exposed to growth factors? No

How are cells re-implanted? Intravenously What are cells mixed with for re-implantation? Plasma and blood Does the clinic provide post-procedure follow-up? Did not disclose How often? Did not disclose Clinic Name: Nepsis: Inbicto Ortholab Location: Tijuana, Mexico. Primary Physician: Fernando Ramirez Del Rio Website: <u>www.nepsisinstitute.com</u> Patients Treated: 900 Cost per procedure: Between \$15,000 and \$25,000

Overview of procedure: Unable to verify Procedure Level. Utilizes autologous, bone marrow derived stem cells that are re-implanted via a Level 1 or 2 injection process.

Conditions Treated:

Neurodegenerative diseases, Cerebral Palsy, Spinal Cord Injuries, Kidney failure, Brochiectasis, Emphysema, Cardiovascular, bilateral Hearing loss.

Cell Type: Autologous Cell Classification: Mesenchymal Cell Source: Bone Marrow

How are cells isolated? Did not disclose How are cells processed? Did not disclose Are cells cultured? Yes. How long are cells cultured? Did not disclose Are cells exposed to growth factors? Did not disclose

How are cells re-implanted? Intravenous drip, intrathecal infusion, catheterization or direct implantation depending on condition treated. What are cells mixed with for re-implantation? Did not disclose Does the clinic provide post-procedure follow-up? Did not disclose How often? Did not disclose



Clinic Name: EmCell Location: Kiev, Ukraine Primary Physician: Alexander A. Smikodub, Maria P. Demchuk & Alla V. Novitskava Website: www.emcell.com Patients Treated: 5000 Cost per procedure: Did not disclose.

Overview of procedure: Unable to verify Procedure level. Utilizes allogeneic, fetal tissue derived (embryonic) stem cells that are implanted via a Level 1 injection process.

Conditions Treated:

ALS, AIDS, Alzheimer's, disease Anemia, Anti-Aging, Arterial Hypertension, Cell Source: Fetal tissue Cancer, Diabetes, Muscular Dystrophy, Multiple Sclerosis, Parkinson's, Rheumatoid Arthritis, Cohn's Disease

Cell Type: Allogeneic Cell Classification: Embryonic

How are cells isolated? Did not disclose. How are cells processed? Did not disclose. Are cells cultured? Did not disclose. How long are cells cultured? Did not disclose. Are cells exposed to growth factors? Did not disclose.

How are cells re-implanted? Intravenous injection. What are cells mixed with for re-implantation? Saline. Does the clinic provide post-procedure follow-up? Did not disclose. How often? Did not disclose.



Clinic Name: Regenocyte Location: Dominican Republic Primary Physician: Zannos Grekos, MD Website: <u>www.regenocyte.com</u> Patients Treated: Did not disclose Cost per procedure: \$65,000

Overview of procedure: Unable to verify Procedure Level. Utilizes autologous, peripheral blood derived stem cells that are re-implanted via a Level 2 injection process.

Conditions Treated:

Cardiac disease, Peripheral circulation, Renal insufficiency, Pulmonary disease, Dementia, Metabolic Diseases.

Cell Type: Autologous Cell Classification: Hematopoietic Cell Source: Peripheral blood

How are cells isolated? Did not disclose. How are cells processed? Did not disclose. Are cells cultured? Yes. How long are cells cultured? Did not disclose. Are cells exposed to growth factors? Did not disclose.

How are cells re-implanted? Direct delivery in heart muscle via catheter or into sub-segmental pulmonary or renal arteries. What are cells mixed with for re-implantation? Did not disclose. Does the clinic provide post-procedure follow-up? Did not disclose How often? Did not disclose.



Clinic Name: Maison de Sante Clinic * Location: Lima, Peru Primary Physician: Jorge Tuma, MD ** Website:<u>WWW.MAISONDESANTE.ORG.PE</u> Patients Treated: 800 Cost per procedure: \$6,000

Overview of procedure: Level 1 procedure that utilizes autologous, bone marrow derived stem cells that are re-implanted via a Level 2 injection process.

Conditions Treated:

Terminal heart failure, Refractory angina, Ischemic Heart failure, Type I & II Diabetes, Chronic Stroke, Alcohol Hepatic Cirrhosis, Parkinson's disease, Pulmonary emphysema.

Cell Type: Autologous Cell Classification: CD34 Total Mononuclear cells Cell Source: Bone Marrow

How are cells isolated? Centrifuge with Ficol or Hess Hidroxietil starch How are cells processed? Centrifuge. Are cells cultured? No. How long are cells cultured? None. Are cells exposed to growth factors? No.

How are cells re-implanted? Endovascual catheter. What are cells mixed with for re-implantation? Blood and plasma. Does the clinic provide post-procedure follow-up? Yes How often? Per ICMS Guidelines

* The Maison De Sante Clinic is a participant in the ICMS Open Treatment Registry which provides long-term patient outcome and complications tracking.

** Dr Jorge Tuma is a member of the ICMS and serves on the Laboratory Advisory Board for the Society.



Clinic Name: Miplant Stem Clinic * Location: Seoul, Korea Primary Physician: Jaewoo Pak, MD ** Website: Patients Treated: Less than 50 Cost per procedure: \$6,500

Overview of procedure:

Level 1 procedure that utilizes autologous, adipose (fat)derived stem cells that are re-implanted via a Level 2 injection process.

Conditions Treated:

Orthopedic conditions: Osteoarthritis, Knee damage, Meniscus tears.

Cell Type: Autologous Cell Classification: Mesenchymal Cell Source: Adipose (Fat)

How are cells isolated? Collagenase Enzyme and centrifuge How are cells processed? N/A Are cells cultured? No How long are cells cultured? No Are cells exposed to growth factors? No

How are cells re-implanted? Intra-articular injection What are cells mixed with for re-implantation? Platelet products. Does the clinic provide post-procedure follow-up? Yes. How often? As per ICMS Guidelines: The Clinic participates in the ICMS Open treatment Registry.

* This clinic participates in the ICMS Open Treatment Registry which provides long-term patient outcome and complications tracking.
** Dr Pak is a member of the ICMS and serves on the Institutional Review Board of the Society.



Clinic Name: Stem Cell Biotherapy Location: Zona Rio, Mexico. Guatemala City, Guatemala. Primary Physician: Did not disclose. Website: <u>www.stemcellbiotherapy.com/</u> Patients Treated: 200 Cost per procedure: \$25,000

Overview of procedure: Level 1 procedure that utilizes allogeneic, cord blood derived stem cells. Unable to verify Implantation Level.

Conditions Treated:

ALS Alzheimer's Anti-Aing Autism Muscular Dystrophy Cancer Cardiac Disease Cerebral Palsy , COPD , Crohn's Disease, Diabetes, Kidney Disease, Macular Degeneration, Multiple Sclerosis, Parkinson's disease, Primary Lateral Sclerosis Rheumatoid Arthritis Spinal Cord Injuries & Stroke

Cell Type: Allogeneic Cell Classification: Hematopoietic Cell Source: Umbilical cord blood.

How are cells isolated? Did not disclose. How are cells processed? Cell are incubated. Are cells cultured? Did not disclose. How long are cells cultured? Did not disclose. Are cells exposed to growth factors? Did not disclose.

How are cells re-implanted? Did not disclose. What are cells mixed with for re-implantation? Did not disclose. Does the clinic provide post-procedure follow-up? Did not disclose. How often? Did not disclose.

Notes

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The clinic stats that it "uses stem cells that are derived exclusively from human umbilical cords from full term births. Clinic assures patients that cells are collected under informed consent donation. The clinic further asserts that the cells have sent to a third party laboratory (did not state lab name) and tested for cell type, count, viability, purity, clonogenic capacity, differentiation capacity and safety. After external testing, the stem cells are tested, purified and differentiated into various cell lines at the clinic's in-house laboratory. Additionally, the clinic says that it has developed proprietary "condition specific administration" protocols that are tailored to each patient to maximize the targeting of cells to areas of need." Clinic Name: Servicio de Investigaciones en Medicina Regenerativa - Sanatorio UOCRA * Location: Buenos Aires, Argentina Primary Physician: Alejandro Mesples, MD ** Website: Patients Treated: Less than 50 Cost per procedure: \$15,000

Overview of procedure:

Level 1 procedure that utilizes autologous, bone marrow derived stem cells and re-implants them via a Level 2 injection process.

Conditions Treated:

Diabetes (type 1), Critical limb ischemia, Myocardial infarction. Cell Type: Autologous Cell Classification: Mesenchymal Cell Source: Bone Marrow

How are cells isolated? Centrifuge. How are cells processed? Not processed. Are cells cultured? No How long are cells cultured? Cells are not cultured. Are cells exposed to growth factors? No.

How are cells re-implanted? Peripheral intra-arterial transplant. What are cells mixed with for re-implantation? Mononuclear cells of bone marrow with autologous plasma. Does the clinic provide post-procedure follow-up? Yes. How often? According to ICMS Guidelines.

* The Servicio de Investigaciones en Medicina Regenerativa - Sanatorio UOCRA is a participant in the ICMS Open Treatment Registry which provides long-term patient outcome and complications tracking.
** Dr Alejandro Mesples is a member of the ICMS and serves on several ICMS advisory boards.



Conclusion



The simple conclusion for this report is that the stem cell landscape remains problematic for patients. We have endeavored in this report to provide observational based method to compare clinics and procedures on some of the most basic and critical elements of these therapies. While new clinics have appeared across the globe to offer treatments, it remains nearly impossible to accurately compare and contrast treatments, much less make an informed decision about which procedure may be best for a patient's condition.

That said, this report does evidence the growth of the global stem cell market. With 22 reporting clinics, we have seen that 88% of these procedures utilize autologous stem cells. Additionally, there appears to be a growing level of procedural complexity about the method by which stem cells are processed and injected.

While we are made optimistic by the openness of several clinics, we remain concerned about the overall level of transparency. Without insight into even simple elements of the procedures (i.e. stem cells source or re-implantation methods) it is nearly impossible to provide an apples-to-apples guide for patients or clinicians.

We feel it is critical for the future of stem cell therapies that there be not only a level of transparency, but also of peer oversight and review. We urge stem cells clinics around the world to review and adhere to the ICMS Clinical, Lab Practice and re-Implantation Guidelines, and to participate in the ICMS Open Treatment Registry.

Our goal is to advance safe and effective stem cell therapies. Our goal can only be accomplished if stem cell clinics everywhere embrace transparency, adhere to guidelines and participate the registry.

Join us. www.cellmedicinesociety.org



About the International Cellular Medicine Society.

Representing physicians and researchers from over twenty countries on all six continents, the ICMS is nonprofit organization dedicated to advancement of safe and effective stem cell therapies.

The ICMS achieves its mission through:

The publication of best practices standards for the collection, processing and reimplantation of adult stem cells. These comprehensive <u>Guidelines</u> are written are written and reviewed by physicians and researchers actively involved in the translation of stem cells in the clinical setting. The ICMS currently publishes <u>Lab Practice</u>, <u>Clinical</u> and <u>Re-</u><u>Implantation</u> best practice standards.

The management of <u>Treatment Registries</u> that provides long term outcome and complications tracking for patients who have received stem cell therapies. Through the consistent and scheduled patient follow up, the ICMS <u>Open Treatment Registry</u> provides the independent evaluation of the safety and efficacy of stem cell procedures.

The <u>Accreditation</u> of stem cells clinics. In accordance with the standards established in the Clinical Guidelines and Lab Practice Guidelines, the ICMS provides a strict <u>Accreditation Process</u> that includes the certification of cell lines and laboratories to assure that accredited clinics maintain the highest possible medical and scientific standards.

The hosting of educational websites. Through its main site, <u>CellMedicineSociety.org</u> the ICMS provides news, research and information essential for physicians and researchers. Through <u>StemCellQuestions.com</u>, the ICMS has created a forum whereby patients can inquire about diseases, conditions and stem cells procedures that are answered by qualified MD's and PhD's.

The hosting of professional medical conferences. Each November, the ICMS hosts a stem cells focused symposium that centers on physicians and researchers who are actively using stem cells to treat patients and cure diseases. The next ICMS conference is scheduled for November 11, 2010 at the M Resort in Las Vegas.

Membership in the ICMS is free and open to any interested physician or researcher.

Please Join the ICMS, and help define the future of cell based medicine.

Stem Cell Clinics Evaluated

The follow clinics wrote back, and provided sufficient data to be included in the survey

Regenobody Regencell EmCell Norbet Sass XCell Center Stem Cell Biotherapy Tiantan Puhua Stem Cell Clinic Cell Medicine Clinics Beijing Hongtianji Neuroscience Academy TheraVitae Regenocyte Instituto Brazzini Radiologos Maison De Sante Nepsis Institute Rejuvenare **Regenerative Medicine Institute** Wendeng Orthopedics Hospital StemCell RegenMed International Stem Cell Institute Instituto de Medicina Regenerativa Servicio de Investigaciones en Medicina Regenerativa

The following clinics responded to the initial inquiry of the patient, but failed to respond to the questions posed by the patients:

Medra Steenblock Research Institute

The following clinics did not respond to any inquiry from the patients.

Healthcare Solutions International Shenzhen Beike Biotechnology Bangkok Stem Cell StemCell.md Zandcell.com



Glossary of Terms

Autologous Stem Cells:

Autologous means that the patient's own stem cells are used.

Allogeneic Stem cells:

Allogeneic treatments utilize the stem cells from another patient. While these cells may be more potent that the patient's own stem cells (especially if the patient is ill), because of theoretical risks of transmitting genetic (inherited) disease and rejection.

Hematopoietic:

Hematopoietic stem cells are programmed to make new blood and also seem to have an ability to create new blood vessels. The research would suggest that their biggest strength is in cardiac and vascular applications.

Mesenchymal Stem Cells: MSC are cells found in many local tissues that can become other cells and help to coordinate repair responses. They have been used extensively in many applications including cardiac, orthopedic, and other areas.

Bone Marrow:

The most common collection site for bone marrow is near the posterior superior iliac spine (PSIS). However, this procedure can often yield significant variability in yield based on the variability in the thickness of the marrow cavity.

Ficol Gradient:

A technique where the cells are centrifuged in a special gel that will allow some cells to penetrate deeper into the gel while the lighter cells stay on top. The cells of a certain weight can then be selected out by removing the layer that corresponds to the cell of interest.

Incubation:

Incubation is the time spent by cells in culture. Long term incubation, meaning beyond 30 days may increase the risk of cell becoming cancer forming (transformed). As a result, ICMS does not recommend the culture of stem cells beyond 30 days.

Peripheral Blood Apheresis: This is a way of collecting stem cells using a machine to process blood from a vein. The type of stem cells collected is usually Hematopoietic. as Cells Mesenchymal Stem generally do not circulate in the bloodstream. Oftentimes the patient is given a mobilizing drug to bring cells from the bone marrow into the blood

Centrifugation:

Usually multiple steps whereby cell populations are separated from each other by gravity. Intra-Arterial Direct to Tissue: Direct tissue injection into the damaged tissue is the most scientifically credible injection method. It is also the most technically challenging, requiring a medical specialist with interventional experience to deliver cells.

Direct Tissue Injection:

Injection into the damaged tissue is the most scientifically credible injection method. It is also the most technically challenging, requiring a medical specialist with interventional experience to deliver cells.

Intravenous Delivery:

Delivery of adult stem cells means that many cells will end up in the lungs, not other tissues. This is called a "pulmonary first pass" effect.

Subcutaneous Injection: The ICMS knows of little research that would support that stem cells injected under the skin would have a therapeutic effect at a distant site like heart, brain, lungs, pancreas, joints, etc. There is considerable research showing effectiveness in cosmetic and reconstructive procedures.

Intrathecal injection (often simply called "intrathecal"):

An injection into the spinal canal (intrathecal space surrounding the spinal cord), as in a spinal anaesthesia or in chemotherapy or pain management applications.

