資料２

2012年12月14日
厚生労働省
再生医療の安全性確保と推進に関する専門委員会

海外における規制外診療の実態

大和雅之

東京女子医科大学
先端生命医科学研究所

Dutch clinic is ordered to stop giving stem cell therapy

Tony Sheldon *Utrecht*

A Dutch healthcare watchdog has ordered a clinic in Rotterdam to stop giving patients a treatment in which patients are injected with stem cells taken from umbilical cord blood. The clinic claims that the injection of stem cells can "target cells in a manner specific to an individual's condition."

A four month investigation into the Preventive Medicine Clinic by the Dutch Healthcare Inspectorate has concluded that the clinic is not providing "responsible care," as it is "unable to demonstrate the origin, suitability, and safety of its stem cells" (www.igz.nl).

Robert Trossel, the clinic's medical director, claims to have treated hundreds of patients, charging about £12 500 (€18 000; $23 400) each. Last week he was reported as saying that the stem cells he uses are safe.

Dr Trossel has six weeks in which to lodge an objection to the inspectorate's decision.

Stem Cell Clinics Online: The Direct-to-Consumer Portrayal of Stem Cell Medicine

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DOI 10.1016/j.stem.2008.11.001

Table 1. Nature of Therapies Offered across Surveyed Websites

Stem Cell Type	Frequency	%
Adult, autologous	9	47
Fetal	6	32
Cord blood	4	21
Embryonic	2	11
Adult, allogeneic	2	11
Adjuncts	0	0
Unspecified	0	0
Stem Cell Source	**Frequency**	**%**
Bone marrow	7	37
Blood or marrow donors	5	26
Peripheral blood	5	26
Fetuses	4	21
Fat	2	11
Unspecified	2	11
Other	3	16
Transplantation Procedure	**Frequency**	**%**
Intrathecal, into the CSF	6	32
Intravenous	6	32
Subcutaneous or intramuscular	4	21
Surgical transplantation	4	21
Catheterization of deep body vessels	3	16
By mouth	1	5
Topical	1	5

nature REPORTS stem cells
the news behind the science, the science behind the news

News Feature

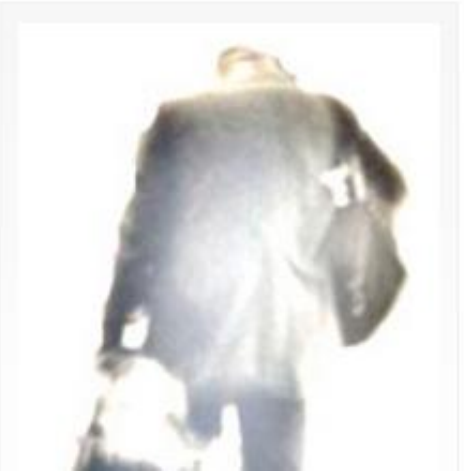
Nature Reports Stem Cells
Published online: 5 June 2008 | doi:10.1038/stemcells.2008.89

Stem cell researchers face down stem cell tourism

Bryn Nelson[1]

A variety of international efforts hope to warn patients off unregulated treatments

In April, a paralysed man returning to Colorado from experimental stem cell therapy in India said he could feel the waistband of his pants for the first time in years. Like others before him, he couldn't say how many cells he had received or how his treatments had worked. Nor had his doctor published any details.



In the end, members of CareCure , an online forum for patients, caregivers and their advocates were left to parse through a tantalizing yet frustratingly incomplete anecdote once again.

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Such 'stem cell tourism', where people travel thousands of miles and pay thousands of dollars to receive unregulated care, is nothing new, and for years Young has been one of the few scientists on an educational campaign. Now, with more stem cell applications being pushed toward clinical trials, the international research community is stepping up.

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Commentary

Nature Reports Stem Cells
Published online: 3 December 2008 | doi:10.1038/stemcells.2008.151

Offshore stem cell treatments

Sorapop Kiatpongsan[1,2,3] & Douglas Sipp[4,5]

Costs, risks, benefits, and a call for regulation

For some patients with debilitating illnesses, hope seems only a plane ride away. Though the scientific mainstream has dismissed stem cell clinics operating outside standard medical practice, patients continue to go. Patients and providers accuse the biomedical establishment of inaction and excessive caution; the biomedical establishment accuses providers of selling false hope to patients who have exhausted all available options. The resulting impasse arguably stands as the greatest current threat to the advancement of stem cell therapies, and the strongest evidence of the need for regulatory frameworks capable of addressing the needs of the diverse stakeholders in the 'offshore' stem cell drama.

Stem cells have risen to fame for their great medical promise. It is a promise that remains to be fulfilled. In countries around the world, however, a growing number of physicians are

This free market approach to experimental medicine, in which doctors and entrepreneurs exploit both patient trust and the dearth of cell therapy regulations in many countries, seems destined to end badly.

Doug Sipp, RIKEN Center for Developmental Biology and Kyoto University

nature REPORTS stem cells
the news behind the science, the science behind the news

Commentary

Nature Reports Stem Cells
Published online: 23 September 2009 | doi:10.1038/stemcells.2009.125

The rocky road to regulation

Doug Sipp[1]

Why unproven, risky medical practices elude legal restrictions

China
Thailand
India
United States

Doug Sipp, RIKEN Center for Developmental Biology and Kyoto University

Trading on hope

Jane Qiu investigates the thriving business of selling stem cell transplants as cure-alls for debilitating diseases.

Hungarian police arrested an American, two Ukrainians and a Hungarian in late July as they were planning to perform a stem cell transplant on a patient in a Budapest clinic. They were detained under suspicion of administering illegal and untested stem cell treatments. One of the Ukrainians, Yuliy Baltaytis, caused a scandal when his Barbados clinic was closed after the BBC alleged the fetal stem cells used in his procedures were obtained unethically in the Ukraine. The cost of the Budapest procedure, $25,000, betrayed the motivation of the four suspects: injecting stem cells into patients suffering from otherwise incurable diseases is big business.

http://www.nature.com/nbt/journal/v27/n9/full/nbt0909-790.html

Table 1 Centers promoting unproven stem cell treatments

Name/ website	Clinic location(s)
Beike Biotechnology http://www.beikebiotech.com/	China
NuTech Mediworld Website not available*	India
Medra http://www.medra.com/	Dominican Republic
Stemedica http://www.stemedica.com/	Not provided
Regencell http://www.regenecell.com/	Thailand, Mexico
Regenocyte http://regenocyte.com/	Florida
Repair Stem Cell Institute http://repairstemcells.org/	China, Dominican Republic, Germany, Israel, Latin America, Portugal, Thailand
Theravitae http://www.theravitae.com/	Thailand

*Websites obtained form source materials no longer available.

STEM CELLS®

TRANSLATIONAL AND CLINICAL RESEARCH

Medicine on the Fringe: Stem Cell-Based Interventions in Advance of Evidence

ALAN C. REGENBERG,[a] LAUREN A. HUTCHINSON,[b] BENJAMIN SCHANKER,[c] DEBRA J. H. MATHEWS[a]

[a]Johns Hopkins Berman Institute of Bioethics, Johns Hopkins University, Baltimore, Maryland, USA; [b]The London School of Hygiene and Tropical Medicine, University of London, London, United Kingdom; [c]Boston University, Boston, Massachusetts, USA

Stem cell-based interventions (SCBIs) offer great promise; however, there is currently little internationally accepted, scientific evidence supporting the clinical use of SCBIs. The consensus within the scientific community is that a number of hurdles still need to be cleared. Despite this, SCBIs are currently being offered to patients. This article provides a content analysis of materials obtained from SCBI providers. We find content that strains credulity and almost no evidence of SCBIs being delivered in the context of clinical trials. We conclude that until scientific evidence is available, as a general rule, providers should only offer SCBIs in the context of controlled clinical trials. Clients should be aware that the risks and benefits of SCBIs are unknown, that their participation is unlikely to advance scientific knowledge, and they are likely to become ineligible to participate in future clinical trials of SCBIs. We recommend steps to promote patient education and enhance global oversight. STEM CELLS *2009;27:2312–2319*

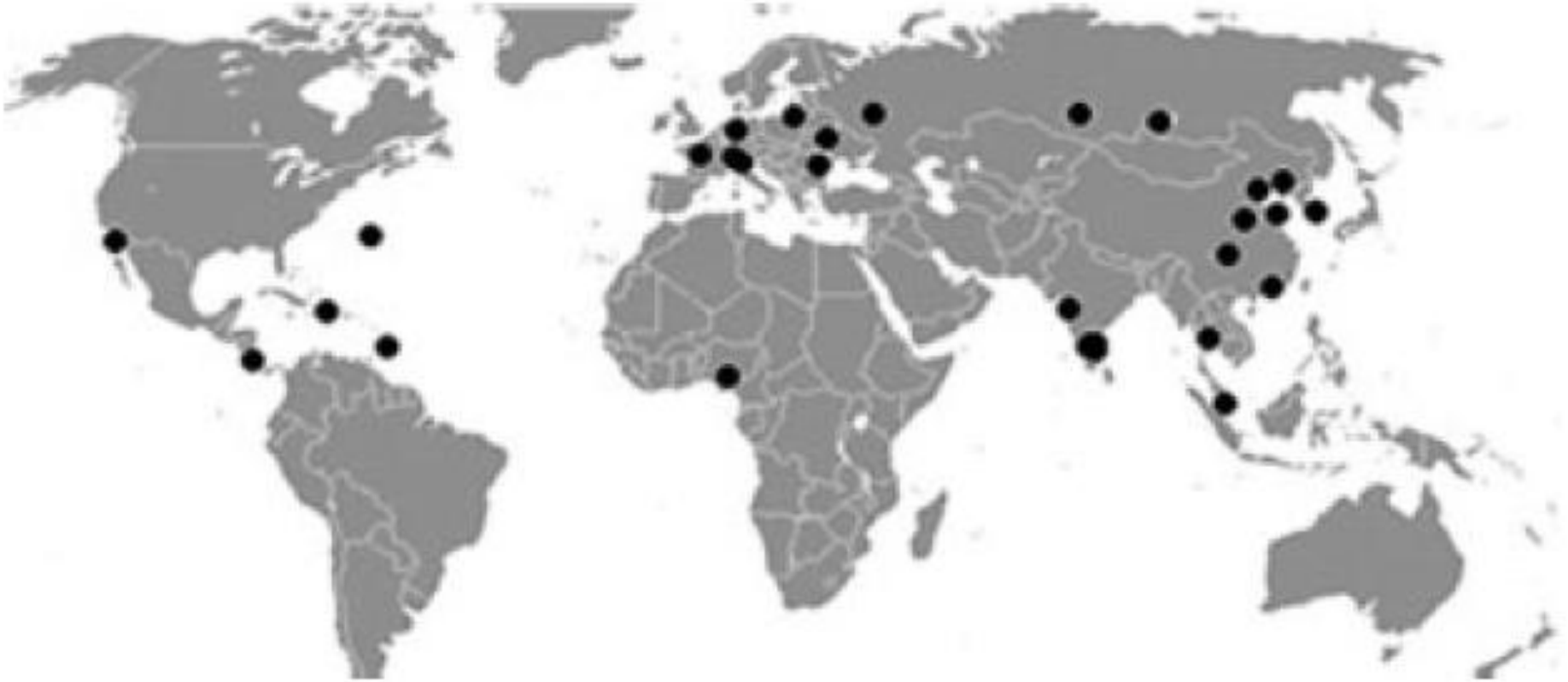
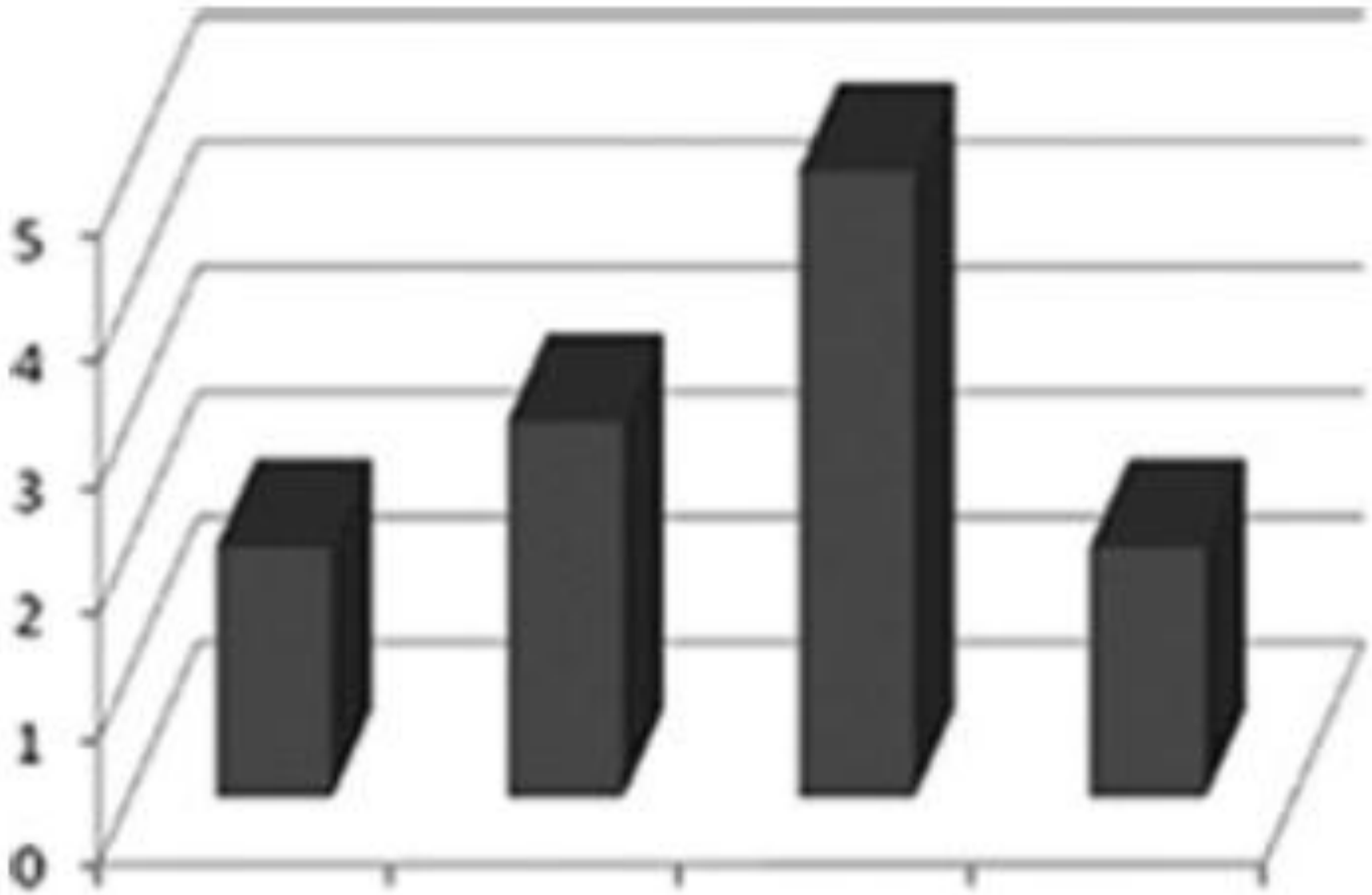


Figure 1. Intervention delivery locations.

Table 1. Available content by provider

Provider	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23
Credentials																							
Medical Degree (MD/MBBS)			X	X	X	X	X		X	X		X	X	X	X	X			X	X			
Other academic credentials (PhD/DSc)			X	X	X	X		X	X	X		X	X		X	X				X			
Prof. credentials/fellowships (FACC, FACS, FRCS)						X									X					X			
Generic prefix (Dr.)		X									X										X		X
Cell sources																							
Cord Blood (4)	X			X										X			X						
Adult, Autologous (7)									X	X				X	X	X				X		X	
Adult, Allogeneic (2)																				X			X
Adult, Unspecified (3)			X					X													X		
Fetal Tissue (7)		X	X			X	X						X					X			X		
Human Embryonic (3)					X			X										X					
Other (3)											X	X						X					
Xenotransplantation (2)																			X		X		
CBI method																							
Condition specific methods (e.g., diagnosis)	X	X	X	X		X			X				X					X	X	X	X		
Patient specific methods (e.g., condition severity)	X		X			X														X			
Injected/surgically implanted directly into affected site			X	X		X			X				X		X	X					X		
Injected into Spinal Cord Fluid			X	X					X	X			X										
Injected Intravenously				X		X	X								X*								
Injected Intraarterially									X														
Injected subcutaneously							X																
Unspecified injection																			X		X		
Cell Quality Assurances																							
Purity (only stem cells)	X	X	X			X				X							X						
Infection free/sterile conditions for manufacture	X		X		X	X				X		X	X			X	X						
Cell potency/differentiation capacity	X		X											X			X						
Manufactured in adherence with standard practices	X				X					X			X			X	X				X		
Third party testing	X					X																	X
Benefits																							
Clinically significant benefits for a majority	X					X	X								X						X		
Range of outcomes, benefits for a majority		X	X	X	X				X	X												X	
Benefits exceed current standard treatments			X						X				X								X		
Vague positive claims								X			X	X	X	X		X	X	X	X	X			X
Not a cure		X													X							X	
Benefits not guaranteed				X						X								X					
Risks																							
No risks/no side effects							X					X										X	
No reported side effects/adverse events among clients receiving their intervention	X		X		X									X	X			X					
No serious risks, only minimal risks/typical risks from implantation		X	X		X				X				X		X		X	X			X		
Both significant and minor risks										X						X							
No risk of immune rejection						X	X									X	X				X		
No risk of teratoma						X																	
Provider	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23



*based on 12 providers indicating intervention costs

Figure 2. Cell-based intervention costs.

Table 2. Information about cell-based intervention costs

	Number of providers out of 23
No information about cell-based intervention costs	8
Costs available on further client evaluation	3
Range of costs depending on diagnoses and the intervention delivery method	6
Single specific cost	6

Table 3. Conditions for which providers offer cell-based intervention

Multiple sclerosis	16
Parkinson disease	16
Stroke	15
Diabetes	13
Spinal cord injury	12
Heart disease	11
Cerebral palsy	11
Traumatic brain injury	8
Amyotrophic lateral sclerosis	8
Alzheimer disease	6
Duchenne muscular dystrophy	6
HIV/AIDS	3

Table 4. Case studies

Country of origin (n = 480)	
United States	181 (38%)
Italy	60 (13%)
Romania	49 (10%)
Spain	18 (4%)
China	17 (4%)
The Netherlands	14 (3%)
United Kingdom	13 (3%)
Canada	10 (2%)
Germany	10 (2%)
Australia	10 (2%)
Japan	9 (2%)
Greece	6 (1%)
Singapore	5 (1%)
Saudi Arabia	4 (1%)
South Africa	4 (1%)
India	4 (1%)
Other (29 countries)	52 (11%)
Indications (n = 491)	
Amyotrophic lateral sclerosis	167 (34%)
Spinal cord injury	113 (23%)
Multiple sclerosis	67 (14%)
Heart disease	38 (8%)
Cerebral palsy	30 (6%)
Cancer	16 (3%)
Stroke	15 (3%)
Parkinson disease	11 (2%)
Traumatic brain injury	8 (2%)
Hepatitis C and liver fibrosis	2 (<1%)
Anemia	2 (<1%)
Diabetes (type 2)	2 (<1%)
Other	20 (4%)

Stem-cell therapy faces more scrutiny in China

But regulations remain unclear for companies that supply treatments.

The Chinese Ministry of Health has implemented regulations on the clinical application of cutting-edge therapies such as stem-cell injections.

Stem-cell scientists in China contacted by *Nature* hope that the rules may help to curtail a growing trade in unproven treatments that attract patients from around the world, risking their health and potentially damaging the reputation of stem-cell research.

http://www.nature.com/news/2009/090513/pdf/459146a.pdf

The new regulations, which came into effect on 1 May, designate all forms of stem-cell therapy as 'category 3' medical technologies — those deemed "ethically problematic", "high risk" or "still in need of clinical verification". The ministry will take direct responsibility for regulating all category-3 procedures, which include gene therapy, surgical treatment of mental disorders or drug addiction, and sex changes.

Institutions wishing to offer stem-cell therapies must first demonstrate safety and efficacy in clinical trials; the treatment will then be assessed by a ministry-approved regulator. Institutions failing that process must wait 12 months before reapplying. Although the penalties for not adhering to these rules have not been made explicit, institutions that transgress are likely to face fines or have their permit to practice medicine revoked, says Renzong Qiu, a bioethicist based at the Peking Union Medical College in Beijing.

Murky area

China already has experience in regulating cutting-edge technologies by assessing clinical trials and conducting ethical reviews. It was the first country to give governmental approval for a gene-therapy treatment, one produced by SiBiono GeneTech in Shenzhen that targets head and neck cancers.

But stem-cell therapy is a murkier area. Some researchers worry that medical institutions will be able to circumvent the regulations by calling their therapies research, even though they are charging patients and not carrying out the rigorous monitoring required by clinical-trial protocols. If those institutions have sought official approval, it comes from local governments or institutional review boards, which do not have the expertise to properly assess the treatment, says Hu.

From interviews with scientists and physicians, Qiu estimates that there are 100–150 clinics claiming to offer stem-cell therapies in China. But it is not yet clear whether companies supplying the stem cells will be also be subject to the regulations.

Shenzhen-based Beike Biotechnology is China's most prominent stem-cell therapy company, providing adult stem cells and umbilical-cord stem cells to a network of 27 clinics worldwide. The company also acts as a first point of contact for patients. Luca Ricci, the Beike representative at Zhejiang Xiaoshan Hospital in Hangzhou, told *Nature* that his job was to "work in the hospital as an interpreter, taking care of the patient before and after they arrive." Beike's medical officer, Kara Zhang, says that she visits patients to provide medical consultations.

The company claims that more than 4,000 patients have been treated for disorders including autism, cerebral palsy, multiple sclerosis and spinal-cord injury. Over the past year, several media reports have claimed that the company's stem-cell treatments have restored sight to blind children.

But the treatments have not been subject to controlled clinical trials to assess whether they are effective and safe — and they don't come cheap. Earlier this year, Beike quoted a price of US$26,300 for an initial course of six stem-cell injections to treat a patient with spinal muscular atrophy, with additional injections costing $3,500 each.

Beike Biotech

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Beike Biotech

MAIN MENU

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Welcome to Beike Biotech

Beike Biotechnology is a leading biotechnology company whose scientists have been dedicated to the development and commercialization of adult stem cell therapies since 1999. The company currently produces a full line of stem cell products derived from umbilical cord, cord blood, and bone marrow stem cells. Beike's proprietary processing and quality assurance technologies prepare the cells for use in treating a variety of serious medical conditions including ataxia, brain injury, cerebral palsy, diabetic foot disease, lower limb ischemia, multiple sclerosis, muscular dystrophy, spinal cord injury, and optic nerve damage.

Watch the video introduction to the Shenzhen Beike Biotechnology Company.

Beike's stem cells are derived from healthy donors who are carefully screened for transmissible diseases. The samples are additionally

Global clinical research and technical support network

Beike Biotechnology has provided clinical-grade stem cells and technical support services to over 70 Chinese medical institutions and to countries in Southeast Asia, the Middle East and Europe. Beike Biotechnology's service network includes stem cell storage, stem cell testing, stem cell clinical translation, R&D of stem cell technologies and products, stem cell drug screening, stem cell technology exchange and employee training.

The largest comprehensive stem cell banks in Asia

Beike Biotechnology's first stem cell banks include the Jiangsu, Shenzhen and Anhui stem cell banks, with a total area of 323,000 square feet, a total storage capacity of over two million units and a total investment of nearly $80 million. Beike Biotechnology's second project includes stem cell banks in Liaoning, Henan, Guizhou, and India, with a total designed storage capacity of nearly ten million units.

Strength in Research & Development

Beike Biotechnology has an outstanding stem cell research team that includes over three hundred technical staff and over ten scientists with PhD degrees. Nearly 100 papers have been published in internationally renowned publications including *Nature Reviews Rheumatology* and Stem Cell. Beike Biotechnology owns 21 patents and has undertaken 27 government research projects. Beike Biotechnology was accredited as a national high-tech enterprise and became a member of the International Society for Cellular Therapy (ISCT) in 2009.

Strict quality control systems

Beike Biotechnology has established more than 20 adult stem cell processing laboratories, in accordance with GMP standards, and has been awarded ISO9001 and ISO17025 certificates. Jiangsu Beike's inspection center was accredited by the China National Accreditation Service for Conformity Assessment (CNAS) in 2011, and it is the first adult stem cell processing laboratory accredited by CNAS. Beike Biotechnology also successfully completed on-site evaluation for American Association of Blood Bank (AABB) accreditation

Cell Products

Beike Stem Cell Product Development Pipeline

(As of July 31, 2011)

Product	Indication	Stage	Clinical Trials Identifier
NU215-01	Systemic Lupus Erythematosus	I/II	NCT00698191
NU215-01	Decompensated Liver Cirrhosis	I/II	NCT01342250
NU211-01/NU215-02	Progressive Multiple Sclerosis	I/II	NCT01364246
NU211-01/NU215-02	Hereditary Ataxia	I/II	NCT01360164
NU211-01/NC215-01	Autism	I/II	NCT01343511

Beike Biotechnology's setting records in the stem cell translation

- First to collect the most comprehensive data of clinical safety study on human umbilical cord blood-derived mononuclear cell translation
- First blind patient recovered sight after receiving human umbilical cord blood-derived mononuclear cell translation
- First patient with systemic lupus erythematosus regained health after receiving human umbilical cord-derived mesenchymal stem cell translation

ClinicalTrials.gov

A service of the U.S. National Institutes of Health

Mesenchymal Stem Cells Transplantation for Refractory Systemic Lupus Erythematosus (SLE)

The recruitment status of this study is unknown because the information has not been verified recently.

Verified June 2008 by Nanjing Medical University.
Recruitment status was Recruiting

Sponsor:
Nanjing Medical University

Collaborator:
National Natural Science Foundation of China

Information provided by:
Nanjing Medical University

ClinicalTrials.gov Identifier:
NCT00698191

First received: June 13, 2008
Last updated: June 16, 2008
Last verified: June 2008
History of Changes

Purpose

This study will explore a new approach to treat patients with a medical condition known as systemic lupus erythematosus (SLE) who have previous treatments using a new population of cells with capability to restore a normal immune system that will no longer attack the body.

The stated hypothesis is that the SLE condition is caused by an abnormal immune system that can be restored by replenishing the body v

Survey details stem cell clinics ahead of regulatory approval

NATURE MEDICINE VOLUME 16 | NUMBER 5 | MAY 2010

The 22 clinics on the list purport to treat more than 70 ailments ranging from diabetes to Parkinson's disease and span the globe from Ukraine to El Salvador. A total of nearly 200 companies advertise services involving unproven uses of stem cells online, according to Douglas Sipp, who studies stem cell policy and ethics at the RIKEN Center for Developmental Biology in Kobe, Japan.

Regulators must step up stem cell oversight

A growing number of clinics are offering cell therapies that remain untested in rigorous clinical trials. Although the scientific community has chided the use of unproven treatments, we need less talk and more action in regulating stem cell therapies.

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Schultz likens his clinic to an assisted fertility clinic, which also handles a patient's own stem cells—unfertilized eggs—*ex vivo* before reimplanting them after fertilization. So he feels confident that he can continue to treat patients without a biologics license application or an investigational new drug application. To his credit, Schultz has even started publishing data in peer-reviewed scientific literature (*Curr. Stem Cell Res. Ther.* **5**, 81–93, 2010). The FDA, meanwhile, remains silent.

Unique Cell Treatment Clinic

EN CH DE RU

UCTC
Unique Cell Treatment Clinic

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We treat

- AIDS/HIV
- Alzheimer`s Disease
- Anemia
- Anti-Aging Treatment
- Arterial Hypertension
- Cancer
- Diabetes
- Coronary Heart Disease
- Liver Diseases
- Muscular Dystrophy
- Multiple Sclerosis
- Parkinson's Disease
- SMA

Cell therapy is a progressive treatment of diseases

Prof. Alexander Smikodub MD

Alexander Smikodub Jr. M.D

Welcome to

UNIQUE CELL TREATMENT CLINIC

Our clinic offers the most advanced and the most efficient patented methods of

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FAQs

1. What types of stem cells are used in your clinic?
2. What are the advantages of rehabilitation that you offer?
3. Are there any side effects such rehabilitation?
4. How long does the procedure last?
5. How is the work carried out?
6. How long should the patient stay at the clinic after

http://uctclinic.com/

We treat

Conditions and diseases successfully treated with fetal stem cells

Diabetes Mellitus
New-onset insulin-independent diabetes
Insulin-independent diabetes
Diabetic nephropathy
Diabetic neuropathy
Insulin-dependent diabetes

Blood diseases
Acute and chronic leukosis
Agranulocytosis
Anemia:

- acid deficiency anaemias
- aplastic
- chronic renal insufficiency
- hemolytic (erythropathy, hemoglobulinosis)
- sideropenic, B12- and folic

Leukopenia
Myelodepression
Thrombocytopenia
Myelodysplasia

Oncology
Cancer
Leukosis

AIDS/HIV

Diseases of nervous system
Alzheimer's disease
Amyotrophic lateral sclerosis(ALS)
Encephalopathy
Duchenne muscular dystrophy
Meningoencephalitis sequelae
Multiple sclerosis
Neurotrauma
Parkinson's disease
Pick's disease
Primary and secondary neurodystrophy
Postoperative period in neurosurgery
Spinal muscular atrophy

http://uctclinic.com/we-treat/

Abstinence syndrome
Post-stroke condition

Conditions
Aging
Asthenic syndrome
Cachexy
Chronic fatigue syndrome
Climacterium female
Climacterium virile
Premature aging

Ophthalmological diseases
Best disease
Optic nerve atrophy
Retinitis pigmentosa
Retinopathy of different etiology
Stargardt's disease

Intestine diseases
Colitis of different etiology
Crone's disease
Nonspecific ulcerative colitis

Connective tissue diseases
Systemic lupus erythematosa
Rheumatoid arthritis
Undifferentiated collagenoses

Liver diseases
Chronic hepatitis
Cirrhosis

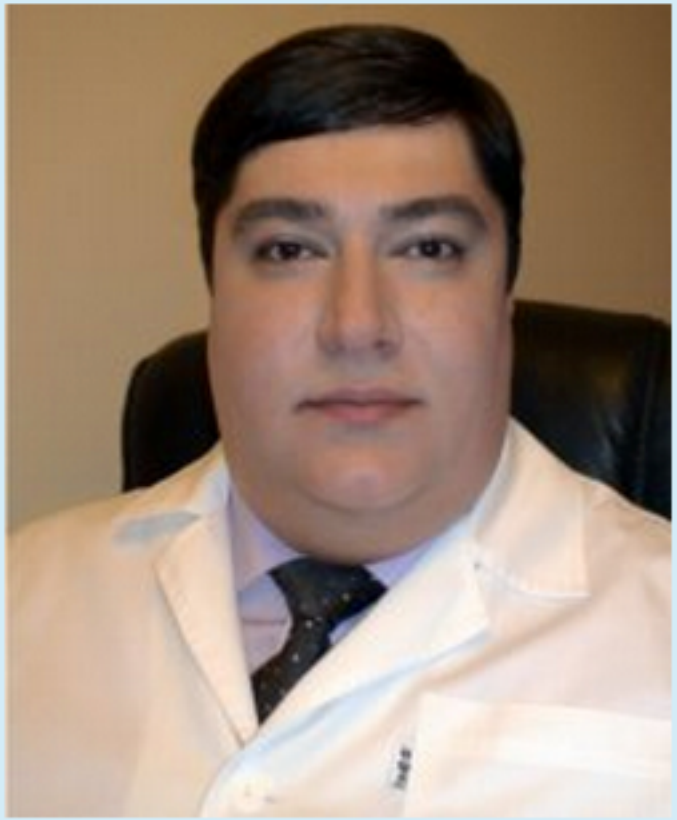
Joints diseases
Deforming arthrosis
Oligo-, mono-, and polyarthritis

Sexual diseases
Fading potency
Male and female sterility

Cardio-vascular diseases
Arterial hypertension
Ischemic heart disease
Heart failure

http://uctclinic.com/we-treat/

About Alexander Smikodub Jr. M.D. & UCTC



Alexander Smikodub Jr. M.D.

UNIQUE CELL TREATMENT CLINIC is a medical center the history of which goes back to 1994. For over 15 years the founder of our clinic Professor Alexander Smikodub Sr. was the head of the clinic developing and introducing unique methods of stem cell treatment. Now his son Alexander Smikodub Jr. continues this unique treatment commenced by his father. During the years of work our clinic has performed about 6 500 transplantations of fetal stem cells. Our treatment has helped prolong life, improve its quality and in many cases completely cure thousands of patients from all over the world (the USA, Italy, Germany, China, the Russian Federation, Poland, etc.), who had lost any hope for recovery.

History of the clinic

UNIQUE CELL TREATMENT CLINIC has a glorious history connected with the invention of medicinal preparations based on fetal stem cells and their clinical application. Here we were the pioneers and remain the leaders.

The scientific potential of our center is the huge knowledge and experience of our specialists and staff, it is a great deal of information published all over the world, it is a big number of reports and lectures at various congresses and conferences, it is scientific degrees and dissertations defended by our employees. By February, 2009 the specialists of our center under the supervision of Professor Alexander Smikodub Sr. and later of his son Alexander **Smikodub** Jr. up to June, 2011, provided medical services to patients from all over the world under the EmCell trademark.

In June, 2011 the company EmCell Embryonic Tissue Center Ltd. was divided between its owners according to their shares. Dr. Alexander Smikodub Jr. restructured his clinical base into a separate clinic with a well-developed infrastructure and a modern laboratory. The clinic provides its services under the **UNIQUE CELL TREATMENT CLINIC** trademark.

However, despite all reorganization processes, the center still has a long scientific history, a wealth of clinical experience and thousands of grateful patients we helped.

Our scientific history

1987	treatment of patients with cytostatic myelodepression and aplastic anemia (filing of patent application).
1991	clinical trials and invention of acquired immune deficiency syndrome (AIDS) and HIV-infection treatment method; filing of patent application in the USA (priority since 1993).
1992	successful application of fetal stem cells (in vivo) in clinical trials for treatment of type 1 and 2 diabetes mellitus, filing of patent application
1993...1994	foundation of the Cell Therapy Clinic of the National Medical University (17 Solomenskaya Str., Kiev, Ukraine). Clinical trials of cell transplants for treatment of different diseases and conditions. First Ukrainian patents granted. The beginning of development of multiple sclerosis treatment methods.
1995	application of fetal stem cells (in vivo) for treatment of amyotrophic lateral sclerosis. First efforts to apply different types of cell suspensions for treatment of muscular dystrophies, in particular Duchenne Muscular Dystrophy

1998...2001	Greek, USA, Russian Federation and Ukrainian patents granted.
1999	Ministry of Healthcare of Ukraine approval of methodological recommendations on application of fetal stem cells in oncology, developed by the clinic.
2000	Ministry of Healthcare of Ukraine approval of methodological recommendations on application of fetal stem cells in diabetes treatment, developed by the clinic.
2001	Ministry of Healthcare of Ukraine approval of methodological recommendations on application of fetal stem cells in hematology, developed by the clinic.
2002	"Most Innovative Work" Award granted by the Scientific Committee of the Annual Meeting of the Society of Medical Innovations and Technology (SMIT) held in Oslo, Norway. The first Dutch patent granted. Ministry of Healthcare of Ukraine approval of methodological recommendations on application of fetal stem cells in endocrinology, developed by the clinic.

2004	Ukrainian and Russian Federation patents granted. Development and patenting of methods of intestine diseases treatment (Crohn's disease, non-specific ulcerative colitis, etc.). Working out of ethical norms on the work with human fetal cells approved by the Ministry of Healthcare of Ukraine.
2005...2007	extension of active clinical and scientific activities, participation in the numerous conferences and congresses, direct participation in the work of international societies and associations, such as Cellular Therapy Society, Cell Transplant Society, Multinational Association of Supportive Care in Cancer, Society for Minimally Invasive Therapy, EASD.
2008	development of methods of fetal cell suspensions application in surgical practice, in particular for treatment of erosive-ulcerative lesions of stomach and duodenum complicated by bleeding. Elaboration of patient surveillance that was declared the best at the 1-st Central European Congress on Surgery (Prague, Czech Republic).
2009	Ukrainian patents granted

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Lik Sprava. 2002;(2):59-63.

[Treatment of anemia in rheumatoid arthritis with transplantation of hemopoietic stem cells from human embryonic liver].

[Article in Ukrainian]

Demchuk MP, Smykodub OI.

Abstract

The article describes chief links of pathogenesis of anemia in rheumatoid arthritis (RA). These include the blood hyperviscosity syndrome, abnormalities of iron metabolism, blockade of iron in the reticuloendothelial system, hemolysis, depression of erythropoiesis. Indices for the hemoglobin peripheral blood, erythrocytes, reticulocytes, platelets in the group of RA patients were analysed together with their changes under exposure to transplantation of hemopoitic stem cells of human embryional liver.

PMID: 12073264 [PubMed - indexed for MEDLINE]

Order from chaos

Nature **466**, 7–8 (01 July 2010) | doi:10.1038/466007b
Published online 30 June 2010

Much tighter regulations are needed to reap the full benefits of stem-cell treatments.

There are at present estimated to be more than 200 clinics worldwide — including more than 100 in China alone — offering what are often unproven stem-cell treatments for scores of disorders including spinal-cord injury, amyotrophic lateral sclerosis and multiple sclerosis (see *Nature* **459**, 146–147; 2009). The potential profits are huge: there is an abundance of patients desperate for miracle cures, and one stem-cell treatment can bring in tens of thousands of US dollars.

Practitioners at these clinics claim that their treatments are safe and effective. But they typically base those claims on little more than patient testimonials and media accounts, and they lack independent oversight. Few offer evidence from controlled clinical studies or from rigorous follow-up of their own patients.

http://www.nature.com/nature/journal/v466/n7302/full/466007b.html

Stem-cell laws in China fall short

The Chinese government's regulations of stem-cell treatments are admirable in principle, but tougher enforcement measures are needed to protect patients.

7 OCTOBER 2010 | VOL 467 | NATURE | 633

Such regulations are sorely needed. A leading bioethicist in China last year estimated that more than 100 laboratories there offer stem-cell procedures, many of them unproven, although some clinics reportedly stopped offering the treatments after the regulations took effect. But the government needs to do more than simply announce rules; it needs to give companies clear instructions for complying with them.

The regulations have made little difference so far to Beike Biotechnology in Shenzhen, China's — and perhaps the world's — most prolific purveyor of stem-cell treatments. Beike develops therapies for disorders ranging from multiple sclerosis to lupus, based on adult and umbilical-cord stem cells. Its treatments, offered by more than 30 hospitals throughout China, have been injected into about 9,300 patients, who pay as much as US$26,000 for the procedure. Roughly half have muscular dystrophy or spinal-cord injuries, but many experts say that stem-cell treatments for those conditions are not ready for clinical use.

http://www.nature.com/nature/journal/v467/n7316/pdf/467633a.pdf

FDA challenges stem-cell clinic

How should clinics that treat patients with injections of their own stem cells be regulated? That question is about to test the jurisdiction of the US Food and Drug Administration (FDA) in a landmark legal battle — and is fuelling a war of words between doctors marketing such therapies and academics who urge caution.

The FDA asserted its authority on 6 August, when it requested a federal injunction from the US District Court of the District of Columbia to prevent stem-cell clinic Regenerative Sciences in Broomfield, Colorado, from preparing its treatments. The company isolates, cultures and processes adult stem cells from a patient's bone marrow or synovial fluid. Doctors then inject the cells to treat fractures, torn tendons and other ailments. The clinic charges patients US$7,000–9,000, carries out about 20 procedures each month, and says it will fight the FDA's injunction. Unlike conventional bone-marrow transplants

Christopher Centeno, medical director of Regenerative Sciences.

CENTENO-SCHULTZ CLINIC

Medicine Society (ICMS), based in Salem, Oregon, an association of 1,100 physicians and patients that he co-founded and of which he is medical director.

Centeno and his supporters say that the FDA's request for an injunction is another blow for stem-cell clinics in their David-and-Goliath struggle with an industry-led alliance that wants to put a stranglehold on stem-cell therapies and restrict individuals' use of their own cells. In an open letter on 30 July, ICMS executive director David Audley accused the International Society for Stem Cell Research (ISSCR), based in Deerfield, Illinois, and including some 3,500 stem-cell researchers, of setting out to close their clinics. Motivated by the interests of a pharmaceutical industry unlikely to profit from the treatments, Audley says, the society wants to "change the laws in all civilized countries to outlaw these therapies". When questioned by *Nature*, however, Audley admitted he had no hard evidence for these assertions.

http://www.nature.com/news/2010/100817/full/466909a.html

Published online 23 November 2010 | *Nature* **468**, 485 (2010) | doi:10.1038/468485a

News

Korean deaths spark inquiry

Cases highlight the challenge of policing multinational trade in stem-cell treatments.

David Cyranoski

LOS ANGELES

The controversy over stem-cell tourism, in which patients travel to other countries for unapproved stem-cell treatments, continues to grow. In June, researchers in Thailand reported finding "strange lesions" in a patient who had died following stem-cell therapy for kidney disease (see ***Nature* 465, 997; 2010**). And in August, an 18-month-old Romanian boy died after receiving a brain injection of stem cells.

RNL Life Science offers patient testimony at its California offices.

D. Cyranoski

Now South Korea is trying to crack down on the practice. Following the recent deaths of two Koreans

東亞日報

幹細胞、海外遠征手術を受けた２人が死亡

LISTEN :

OCTOBER 23, 2010 02:59

KOREAN TEXT

国内で許可されていない幹細胞治療を中国や日本で受けた患者２人が死亡したことが分かった。国会保健福祉委員会の朱昇鎔（チュ・スンヨン）議員（民主党）は２２日、国政監査で、「先月３０日、バイオ企業アール・エヌ・エル・バイオの協力病院の日本の京都ベデスタクリニックで、幹細胞治療剤の投与を受けたイム某氏（７３）が、肺動脈塞栓症で死亡した」という事実を公表した。肺動脈塞栓症とは、血管に流れる浮遊物が血管をふさいで生じる。この患者は、アール・エヌ・エル・バイオと１年間のメディカルツアー契約を結び、日本に渡って治療を受けた。

http://japanese.donga.com/srv/service.php3?biid=2010102313878

国政監査では、アール・エヌ・エル・バイオの幹細胞治療剤の投与を受けた患者が証人として出席し、副作用を証言した。朴ファジョン氏は、「昨年８月１２日、中国延吉のヒーリングセンターで、１回１５００万ウォンでアンチエイジングの施術を受けたが、その後、首にがんができた」と主張した。さらに、朴氏の紹介で、友人のクォン某氏が、糖尿病の治療のために幹細胞注射を受けたが、意識不明になって死亡したという。朴氏は、「アール・エヌ・エルは、『コーディ』と呼ばれる営業社員が別の患者を紹介すれば手当を与える方式で営業している」と話した。これに対して、李ジョンソプ食品医薬品安全庁（食薬庁）バイオ政策局長は、「中国や日本で幹細胞治療を受けた患者２人が死亡した事件が報告された」と確認し、「アール・エヌ・エル・バイオが幹細胞治療剤の臨床試験３件を行っているが、食薬庁が安全性と有効性を検証していない状態だ」と答えた。

アール・エヌ・エル・バイオは、中国、日本、米国など８ヵ所で協力病院を運営し、約８０００人の患者に施術している。しかし、国内で許可されていない医薬品を海外で施術する方式で、現行の薬事法、医療法、

生命倫理法をすべて回避している。営利を目的に患者を誘引する「メディカルツアー」は禁止されているが、海外では効力が及ばない。患者に臨床試験のための寄付金の形式で数千万ウォンの施術費を取り、医療法違反を巧妙に避けているという証言もある。

カトリック大学医学部の呉一煥（オ・イルファン）機能性細胞治療センター長は、「幹細胞が生成される過程で凝集すれば、末梢血管を塞ぐ恐れがある。動物を使った臨床試験で、肺動脈塞栓症やリンパ種のような副作用がすでに学界では知られている」と話した。アール・エヌ・エル・バイオは、「死亡した患者は極めて一部で、幹細胞治療の施術との因果関係は明らかになっていない。手続上、問題がない医療行為だ」と説明した。

「幹細胞バンクは詐欺」、幹細胞研究の第一人者が警告

- 2010年02月21日 15:27　発信地:サンディエゴ/米国

【2月21日 AFP】新生児のへソの緒に含まれる「さい帯血」から取り出した幹細胞を保存して難病の治療に役立てるという、いわゆる「幹細胞バンク」。再生医療の1つとして注目を集めているが、幹細胞研究の第一人者が「幹細胞バンクは詐欺だ」と警告して話題になっている。

現在、多くの国の医療施設では、両親が希望すれば新生児のへその緒を保存できるようになっている。子どもが将来重い病気にかかった場合に、さい帯血から幹細胞を取り出して治療に利用することが目的だ。たとえばタイには、「子どもの健康保険の一種」として3600ドル（約33万円）程度を支払って幹細胞バンクを利用する家庭もある。

しかし、米カリフォルニア（California）州のスタンフォード大学（Stanford University）幹細胞生物学・再生医療研究所（Institute of Stem Cell Biology and Regenerative Medicine）のアービン・ワイスマン（Irving Weissman）博士は20日、全米科学振興協会（American Association for the Advancement of Science、AAAS）の年次大会で、「幹細胞バンクは親たちの善意につけ込んでいるだけ」として警戒するよう呼びかけた。

効果が実証されていない幹細胞を使った治療を手掛ける施設が幹細胞に関する規制が緩い国で多数開設されているとワイスマン博士は指摘する。なおAFPが調べたところ、欧米諸国にも複数の幹細胞バンクのウェブサイトがあることが分かった。

「この種の診療施設では確かに幹細胞を使った治療を行うが、その後は患者任せだ。重い病気で家族と一緒にいるべき患者を家族から引き離して、効果が見込めない治療をする。費用は1回あたり5万～15万ドル（約450～1400万円）程度だろう」と博士は話す。「こんなことは間違っている」

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International Society for Stem Cell Research

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Learn About Stem Cell Treatments

A Closer Look at Stem Cell Treatments Website

Visit the ISSCR's patient information Web site 'A Closer Look at Stem Cell Treatments' to find out what is currently possible using stem cells and what kinds of questions you should ask.

Download the ISSCR Patient Handbook on Stem Cell Therapies

Adult Stem Cell Treatments: Myths and Reality

Read this article by David Scadden on the human clinical applications using adult stem cells.

The ISSCR Clinical Translation Guidelines – What They Mean to You

Dr. Olle Lindvall, chair of the Task Force, talks about the relevance of Guidelines for the Clinical Translation of Stem Cells. Watch the video. Read the Guidelines.

Public Symposium at the 2010 Annual Meeting in San Francisco

A Dose of Reality on Alternative Stem Cell Treatments: What You Don't Know Can Hurt You - A discussion addressing the issues of stem cell tourism. Supported by the California Institute for Regenerative Medicine (CIRM).

JSRM The Japanese Society for Regenerative Medicine 日本再生医療学会

English | Japanese

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ISSCR

International Society for Stem Cell Research (ISSCR) 国際幹細胞学会

ISSCRは、幹細胞研究についての情報交換の促進を促す目的でHarvard大学のLen Zon教授らにより2002年に開設された国際学会です。
これまでに3回の総会が開催されましたが、今年の6月にサンフランシスコで開催された第三回の総会には世界中から2100名の参加者を集めました。幹細胞研究に携わる著名な研究者はほとんどがこの学会のメンバーになっていますし、日本からも多くの方が参加しています。
会員には毎月メールによってニュースレター「パルス」が送られてきてミーティング、ニュース、求人、グラントなどの情報を入手することができます。
ホームページも充実していて、日本再生医療学会のホームページにもリンクさせてもらっています。興味のある方はリンクにあるISSCRのホームページ（http://www.isscr.org/）を訪れてみてください。
またISSCRの作成による、幹細胞研究の基本概念を解説したビデオ「Making Sense of Stem Cells」(21分／英語）をご覧いただけます。日本再生医療学会はISSCRと積極的に提携し、幹細胞研究を通じて再生医療を実現することを目指していくつもりです。

- 「Making Sense of Stem Cells」128kbps （wmv 19.22MB）
- 「Making Sense of Stem Cells」256kbps （wmv 39.12MB）
- 「幹細胞治療について患者ハンドブック」和訳 （外部リンク

ISSCR

International Society for Stem Cell Research

幹細胞治療について患者ハンドブック

ISSCR　幹細胞の臨床応用に関するガイドラインの付録1

2008年12月3日

訳：
監修：

www.isscr.org

L. SOLT/DALLAS MORNING NEWS/CORBIS

Texas governer Rick Perry has received a stem-cell treatment deemed illegal in the United States.

REGENERATIVE MEDICINE

Texas prepares to fight for stem cells

Enthusiasm for unapproved treatments worries regulators.

http://www.nature.com/news/2011/110920/pdf/477377a.pdf

FDA Warns About Stem Cell Claims

"FDA will pursue perpetrators who expose the American public to the dangers of unapproved stem cells."

This article appears on FDA's Consumer Updates page, which features the latest on all FDA-regulated products.

Jan. 6, 2012

http://www.fda.gov/downloads/ForConsumers/ConsumerUpdates/UCM286213.pdf

In December 2011, three men were arrested in the United States and charged with 15 counts of criminal activity related to manufacturing, selling and using stem cells without FDA sanction or approval.

According to the criminal indictment, one of the accused, a licensed midwife who operated a maternity care clinic in Texas, obtained umbilical cord blood from birth mothers, telling them it was for "research" purposes. Instead, the midwife sold the cord blood to a laboratory in Arizona which, in turn, sent the blood to a paid consultant at a university in South Carolina. The owner of the laboratory in Arizona was convicted in August 2011 of unlawfully introducing stem cells into interstate commerce. She faces up to 3 years in prison and a fine of up to $10,000.

The consultant, an assistant professor, used university facilities to manufacture stem cell products. He then sent the products back to the lab, which sold them to a man representing himself as a physician licensed in the U.S. The man then traveled to Mexico to perform unapproved stem cell procedures on people suffering from cancer, multiple sclerosis and other autoimmune diseases.

The three defendants allegedly received more than $1.5 million from patients seeking treatment for incurable diseases.

"Scammers like these offer false hope to people with incurable diseases in order to line their own pockets with money," says Special Agent in Charge Patrick J. Holland of FDA's Office of Criminal Investigations (OCI), Kansas City Field Office. "FDA will continue to aggressively pursue perpetrators who expose the American public to the dangers of unapproved stem cells and ensure that they are punished to the full extent of the law."

Adult stem cell therapies walk the line

Tension between practitioners who believe autologous stem cells should be considered a service and the FDA, which considers some of them biologics, has come to a head in recent months. Laura DeFrancesco investigates.

published for the products approved in Korea nor have the claims been replicated in laboratories outside of the companies.

Elsewhere, a small cadre of companies is trying to make a go of it with autologous stem cells (**Table 1**). Aastrom Biosciences, based in Ann Arbor, Michigan, may be the farthest along; the company reported positive phase 2 results with its autologous bone marrow–derived product (ixmyelocel-T) for critical limb ischemia last November[2] and has initiated phase 3 studies, which are expected to be completed in 2014,

Box 1 Troubled waters

Several companies offering autologous stem cell therapies have run into problems outlined below.

- Regenerative Sciences. This company isolates mesenchymal stem cells from patient bone marrow and delivers them to various sites to treat joint, tendon, ligament or bone pain. The company website claims to have treated 1,300 patients with bone marrow–derived stem cells. In 2008, they received a form 483, later enjoined by FDA to stop treating patients with unapproved treatments. The company sought injunctive relief from the FDA claiming that their therapies are not drugs or biologics, and questioning FDA's ability to regulate such products.
- Young Medical Spa (Lansdale, PA, USA). The enterprise removes adipose tissue from patients, isolates stem cells and returns them to fat to produce a stem cell–enriched sample, which is then injected into breasts and joints. The FDA issued a warning letter in April 2012, after two inspections. Infraction: procedure alters the relevant characteristics of adipose tissue and does not meet homologous-use requirement.
- Intellicell BioSciences (New York). Company prepares adipose-derived stem cells and injects them intravenously into lips, cheeks, knees, scalp, osteoarthritic joints, receding gums. FDA issued a warning letter in March 2012 for not meeting requirements of minimally manipulated or homologous use and for deviations from good manufacturing practice.
- Celltex. Company supplies adult stem cells to physicians in Texas. The FDA issued a form 483 in April 2012 for numerous infractions of good manufacturing practices.
- Six patients in California filed suit against the Korean stem cell company RNL BIO (partner of Celltex), for misrepresentation of fact and elder abuse, among other things. Patient cells were harvested in Korea, sent to China, then Los Angeles, and reimplanted in the patients in Mexico. The case is before the US District Court in Los Angeles.

Box 2 FDA guidelines

Autologous cells are regulated by Center for Biologics Evaluation and Research as human cells, tissues, and cellular and tissue-based products (HCT/Ps) under the authority of Section 361 of the Public Health Service Act, as well as Title 21 of the Code of Federal Regulations (CFR) Part 1271, following a tiered regulatory approach that is based on the degree of risk posed by the products. For lower risk products (so-called 361 products), the regulatory framework focuses on minimizing the risk of transmission of infectious diseases. Higher risk HCT/P products (351 products), those presenting greater risks in their processing or use, are subject to licensure and must be shown to be safe and effective. To receive a 361 designation, a product must: be minimally manipulated, perform the same basic function in the donor as the recipient (homologous use), not be combined with other agents and not have a systemic affect.

Whether there is a need to alter the guidelines is debatable. Joyce Frey-Vasconcells, former deputy director of the FDA's Office of Cellular Tissue and Gene Therapies Division (now a consultant with PharmaNet of Princeton, New Jersey), thinks the FDA has done its job in terms of creating the guidelines, but perhaps not in the dissemination. "I don't think the rules are that onerous, [they] are serving the public very well.... Quite frankly, people are just not aware [of the rules]," she says.

But for those straining under the current regulations, ignoring them may not be the best course of action. Irv Weissman, director of Stanford's Institute for Stem Cell Biology and Regenerative Medicine, says, "If the FDA is overcautious, then our job is to educate the FDA, not do away with it. Doing away with FDA oversight is walking right into the hands of the people who are the most unscrupulous."

まとめ

再生医療の規制外診療は美容外科や他に治療法がない難治疾患など世界中でおこなわれている。

患者が国をまたいで治療を受けている。

欧州、米国、中国、韓国等では規制当局が介入しているが十分な効果は得られていない。

日本でも規制当局による介入が必要と考える。