

# **Unproven therapies, clinical trials and regenerative research**

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**On behalf of the ESCIF SCI research working group**

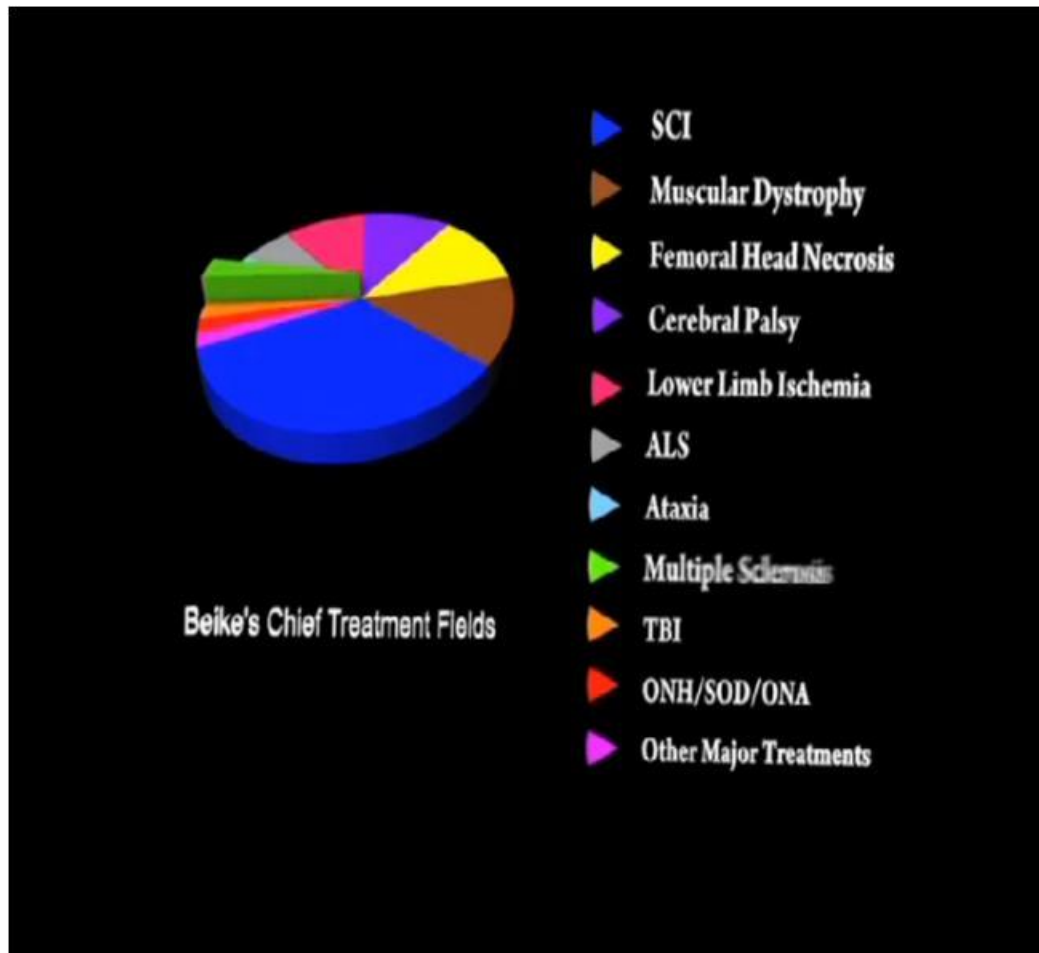
**NOSCoS 2011: Regaining functionality following a spinal cord injury:  
unproven therapies, clinical trials and regenerative research**

# The Stem Cell dream

The collage features several overlapping items:

- MEDRA Brochure:** Titled "Human Fetal Brain Cell Therapy is a medical treatment for Huntington's Disease." It includes a photo of a man and text about the therapy's effectiveness.
- Stem Cell Therapy Brochure:** Titled "Excellence in Stem Cell Therapy" and "THE MECHANISM OF NATURAL HEALING." It discusses regenerative medicine and lists various conditions treated.
- Stem Cell Clinic Website:** A blue-themed website for "Cell Therapy Clinic 'EmCell'". It features a "Welcome to StemCell" message and a list of "AVAILABLE CONDITIONS" such as Alzheimer's, Parkinson's, and Huntington's Disease.
- Neuro-Regeneration Website:** A screenshot of a website titled "Neuro-Regeneration, Repair and Functional Recovery" with a registration form.
- Stem Cell News Article:** A newspaper article from "NEWS REVIEW" featuring a photo of Alasdair Palmer and his wife. The headline reads: "I don't know the science behind my miracle cure – and I don't care". The article discusses stem cell therapy as a "holy grail of medicine" and mentions that Palmer's wife, who has Huntington's Disease, claims the therapy works for her.

# SCI patients as a cash cow...



## DISCLAIMER

Stem cell therapy is an experimental therapy that does not fall into the realm of accepted modalities of treatment

The results reaped from this therapy may differ from person to person

Stem cell therapy aims to bring about a significant improvement in the quality of life

Total number of patients "treated and helped": 6000 patients

Source: [http://www.beikebiotech.com/index.php?option=com\\_content&view=article&id=427&Itemid=100011beike](http://www.beikebiotech.com/index.php?option=com_content&view=article&id=427&Itemid=100011beike) – September 2011.

# ESCIF approach

Two website sections dealing with unproven therapies and research:

- Inform/educate patients
- Encourage feedback for transparency
- Highlight/explain scientific alternatives

[http://escif.org/ESCIF,,extra\\_navi,unproven\\_therapies,unproven\\_therapies.htm](http://escif.org/ESCIF,,extra_navi,unproven_therapies,unproven_therapies.htm)

[http://escif.org/ESCIF,,extra\\_navi,sci\\_research,research\\_for\\_regeneration.htm](http://escif.org/ESCIF,,extra_navi,sci_research,research_for_regeneration.htm)

# 1. Inform/ educate

## a. Characteristics of “unproven therapy”

### What are Unproven Therapies

Although clinical trials are by nature unproven therapies, there are some key differences that need to be understood before enrolling in either. The characteristics of each are summarised below:

An Unproven Therapy has many of the following characteristics:

- Charges the consumer a fee for the therapy
- Provides only anecdotal information (such as personal testimonials) as evidence of success
- Does not provide efficacy and other data to the scientific community
- Is heavily marketed via the internet and glossy brochures.
- Has not been approved by a relevant government body (such as FDA in the US or EMEA in Europe)
- Has not been listed as a clinical trial on a reputable clinical trial website (such as <http://clinicaltrials.gov>)

A Clinical Trial however:

- Is always listed on reputable clinical trial websites (such as <http://clinicaltrials.gov>)
- Does not charge the consumer a fee for the therapy
- Has followed a strict regulatory process in terms of the feasibility of the science and the mitigation of risk to the consumer
- Provides structured studies with large bodies of clinical data for statistically valid evaluation of a therapy to determine safety and efficacy and reports efficacy and other data back to scientific community via peer review.

Latest page update on January 2011 by the Regenerative Research Working Group. For comments or questions, pls email [sci\\_research@escif.org](mailto:sci_research@escif.org)

## b. List of “unproven therapies”, including facts and figures if available

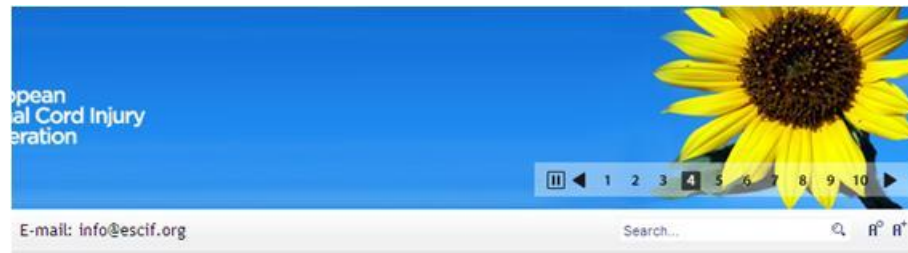
### Unproven Therapies

This section provides a non-exhaustive list of “unproven therapies”. The list does not represent in any way an endorsement of these therapies. Furthermore we recommend against partaking in any therapy that does not adhere to scientific best practices and therefore patient safety and well-being and does not contribute to scientific progress.

However, it should be noted that there is a fine line that divides unproven therapies that follow scientific best practices and those that do not. In order to ensure that scientific best practices have been adhered to, it is important to consult any scientific publications that are available before enrolling.

Therapy	Contact Information	Location	Comments
XCELL CENTER	XCell-Center Institute for Regenerative Medicine Custodisstrasse 3-17 50679 Cologne (X06-Deutz) Germany Director : Dr. Cornelis H. Kleinblossem Phone: ☎ = (0049) 0221 = 8025095 Fax: (0049) 0221 - 8025096 E-mail : <a href="mailto:info@xcell-center.de">info@xcell-center.de</a>	Cologne & Dusseldorf, Germany	Type of therapy: Intrathecal Bone Marrow Autologous Stem Cells.  Current CEO is former CEO of Cells4Health. Cells4Health have a record of stem cell therapies administered in Turkey and Azerbaijan which have resulted in a loss of function.  Although the XCELL website and brochures claim efficacy of their treatment for SCI, no data is made available to the scientific community for peer review.  A clinical trial was planned to take place as of 2011 to underpin the claimed efficacy but is now cancelled (update April 2011).  Update MAY 2011: <a href="http://www.telegraph.co.uk/news/worldnews/europe/germany/8500233/Europes-largest-stem-cell-clinic-shut-down-after-death-of-baby.html">The X-CELL center is shut down after death of baby.</a> For more info see <a href="http://www.telegraph.co.uk/news/worldnews/europe/germany/8500233/Europes-largest-stem-cell-clinic-shut-down-after-death-of-baby.html">http://www.telegraph.co.uk/news/worldnews/europe/germany/8500233/Europes-largest-stem-cell-clinic-shut-down-after-death-of-baby.html</a>
BEIKE BIOTECH	Beike Biotechnology Company Dr. Sean Hu Chairman Beike Biotech Co., Ltd. Shenzhen Hi-Tech Industrial Park 861 3823501818 <a href="http://www.beikebiotech.com">www.beikebiotech.com</a>	Shenzhen, China	Type of therapy: Umbilical Cord Autologous Stems Cells & Intrathecal Bone Marrow Autologous Stem Cells.  Patients are recruited via <a href="http://www.stemcellschina.com">http://www.stemcellschina.com</a> where anecdotal testimonials are published. However, there is no scientific efficacy data published for their Spinal Cord Injury patients.
NUTECH	Nu Tech Medworld 487, Hardev Purli, Near Father Agnel School, Gautam Nagar, New Delhi-110049	Delhi, India	Type of therapy: Embryonic Stem Cells

# 2. Encourage feedback for transparency



## Unproven Therapies

The aim of this section of the site is to help individuals make well-informed decisions when considering taking part in an unproven therapy.

There are many "unproven therapies" available to individuals claiming to offer the chance for functional and sensory return. These therapies can be found in all corners of the world. It is, however, important for individuals to understand the differences between unproven therapies and those therapies which are adhering to best scientific and medical practices. It is also important for individuals to be aware of the risks which can range from financial loss to functional loss!

We invite the individuals who are interested in the progress of science and best practices to pay special attention to the 'Research for Regeneration' section of the website which will provide information on the various lines of research as well as current/planned clinical trials.

If you do decide, however, to undertake any therapy as referred to in the "unproven therapies" section, we strongly recommend that you inform your neurologist, SCI doctor or physiotherapist in order to arrange an appraisal of your current functionality. This will allow them to measure any change following the intervention. In this way the SCI community will be able to gather some information about the therapies that the clinics and organisations offering them are presently unwilling to share.

For those individuals who have taken part in an unproven therapy it is important that you share your experiences, positive or negative, so that the SCI community can learn from these findings. If you would like to confidentially share your experiences please feel free to send an email to [sci.research@escif.org](mailto:sci.research@escif.org).

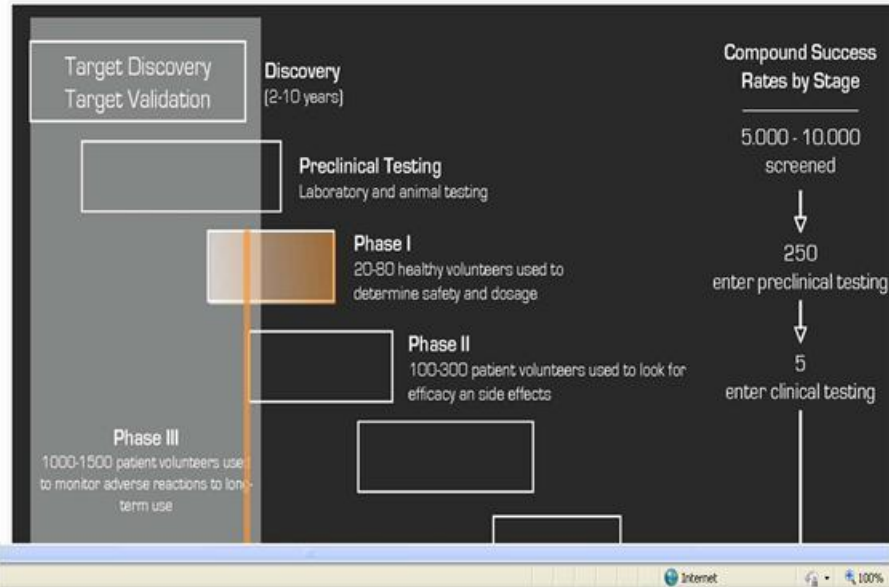
Latest page update on January 2011 by the Regenerative Research Working Group. For comments or questions, pls email [sci.research@escif.org](mailto:sci.research@escif.org)

# 3. Highlight / explain scientific alternatives

## From Science To Medicine

Before any drug or therapy can be applied to humans it must be rigorously tested through a process called clinical translation.

Clinical translation involves taking a treatment through several stages to test for safety and efficacy before it can be approved by medical authorities such as the FDA (US Food and Drugs Administration) or EMA (European Medicines Agency) to be applied to humans. See the following diagram which summarises how the process (in the case of the FDA) works:



## Clinical Trials Overview

Below is a non-exclusive list of clinical trials aimed at the regeneration of the spinal cord in acute, sub-acute and chronic spinal cord injuries. Please note that for the most up to date information about current clinical trials visit <http://clinicaltrials.gov>. This lists are broken up into two sections, acute/sub-acute and chronic spinal cord injury for clarity:

### Acute/Sub-Acute Clinical Trials

Clinical Trial	Description	Location(s)	Contact
<a href="#">Novartis Nogo-A AT1355</a>	Phase I Intrathecal administration of AT1355 (Nogo-A) Neurological Level: C5 to T12 (ASIA A) Duration: 4-14 days post-injury	USA, Canada, Spain, Germany, Switzerland	Novartis Pharmaceuticals 41 61 324 1111
<a href="#">Geron hESC GRNOPC1</a>	Phase I Injection of GRNOPC1 (hESC) Neurological Level: T3 to T10 (ASIA A) Duration: 7-14 days post injury	USA	Geron Corporation <a href="http://www.geron.com/GRNOPC1Trial/">http://www.geron.com/GRNOPC1Trial/</a>
<a href="#">Methodist Hospital System - Riluzole</a>	Phase I/II Oral administration of Riluzole (Rilutek) Neurological Level: C4 to T12 (ASIA A,B,C) Duration: < 12 hours post injury	USA, Canada	The Methodist Hospital System Robert G. Grossman
<a href="#">Niguarda Hospital - EPO</a>	Phase I/II Comparison of erythropoietin(EPO) vs methylprednisolone (MP) Neurological Level: C5 to T12 (ASIA A, B) Duration: < 8 hours	Italy	Niguarda Hospital Tiziana Redaelli MD <a href="mailto:tiziana.redaelli@ospedaleniguarda.it">tiziana.redaelli@ospedaleniguarda.it</a>

### Clinical Trials for Chronic Spinal Cord Injury

Clinical Trial	Description	Location(s)	Contact
<a href="#">Wroclaw Medical University - ner</a>	Phase I Olfactory mucosa ensheathing cell	Poland	Department of Neurosurgery of Wroclaw Medical University <a href="mailto:ner@pau.edu.pl">ner@pau.edu.pl</a>

# Fighting scams...

... can only go through:

- Showing/proving that scams are scams!
  - Facts: transparent objective patient evaluations
  - online tools? Eg. [patientslikeme.com](http://patientslikeme.com)?
- Highlighting and promoting better alternatives:
  - Medical and SCI community collaboration
  - SCI community (self) empowerment

# People with SCI can understand...

- That the cure is not yet available
- That the treatments offered have no proven efficacy and can even be harmful

BUT people with SCI and their family do need:

- A shared sense of urgency
- A massive and coordinated support to research and a fight **AGAINST SCI** and **FOR CURE**

# So ...today's young injured



# Can be tomorrow's breakthroughs



This presentation has been prepared by the ESCIF  
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