SAFETY STUDY OF INTRAVENOUSLY ADMINISTERED HUMAN CORD BLOOD STEM CELLS IN THE TREATMENT OF SYMPTOMS RELATED TO CHRONIC INFLAMMATION

Brian Mehling, MD
Orthopedic Surgeon
CMO, Blue Horizon International
Co-authors: Louis Quartararo, Marine Manvelyan, Paul Wang, Dong-Cheng Wu
Potential Uses of Stem Cells

- Stroke
- Traumatic brain injury
- Learning defects
- Alzheimer's disease
- Parkinson's disease
- Baldness
- Blindness
- Deafness
- Amyotrophic lateral sclerosis
- Missing teeth
- Wound healing
- Bone marrow transplantation (currently established)
- Spinal cord injury
- Osteoarthritis
- Rheumatoid arthritis
- Myocardial infarction
- Muscular dystrophy
- Diabetes
- Crohn's disease
- Multiple sites: Cancers
Stem Cell Application in Orthopedy

• Stem cell research plays an important role in orthopedic regenerative medicine today

• Arthritis literally means "inflammation of a joint"

• Mesenchymal Stem Cells (MSCs) represent a valuable tool for therapy of symptoms related to chronic inflammatory diseases
The Blue Horizon Vision

We foresee stem cell treatments becoming the preferred substitutes for many surgical, pharmacological and rehabilitative medical services.
How do stem cells work?

- Stem cells regenerate injured tissue
- In essence stem cells go to the injured tissue and regenerate to make it healthy or grow new tissue
- The possible uses within medicine are unlimited
- We use non-embryonic stem cells
- Our stem cells are administered via IV and/or a combination of intra articular and intrathecal injection
About Us

- Founded in 2010

- Current facilities: New Jersey/USA, Wuhan/China and Malacky/Slovakia and Berlin/Germany

- Provide autologous and cord blood stem cell transplant therapies for conditions such as: Spinal Cord Injury, Traumatic Brain Injury, Alzheimer's Dementia, Diabetes, Myocardial Infarction, Osteoarthritis, Post Traumatic Arthritis, Rheumatoid Arthritis, Wilson Disease

- Unique concept of Treatment + Scientific Research = Health Improvement
Protocol

- **Preparation of UC-MSCs**
  Collection of umbilical cord bloods from primiparous pregnant women receiving Caesarean section

- **Isolation of MSCs from umbilical cord bloods**
  Washing steps, cells count and re-suspension of $4 \times 10^8$ cells in 5 mL cryopreservation solution (10 % DMSO).

- **Sterility assurance**

- **Transportation**

- **Thawing, cells viability analysis**

- **Infusion**
  2.5 ml (about $2 \times 10^8$) stem cells are used for intra-articular injection. Another 2.5 ml (about $2 \times 10^8$) stem cells are suspended in 100 ml of saline and used for IV.
Our Results in Hard-to-Treat Conditions

BHI Spinal Cord Injury Patients

- 90% of 89 SCI patients reported improvement

BHI CVA (Stroke) Patients

- 94% of 97 CVA patients reported improvement
Traumatic Brain Injury II, Car Accident

21 year old male

Before
- Traumatic Brain Injury level II
- T11-12 Vertebral Fracture,
  Spinal Cord Injury
- Lower Extremity Muscle strength: 0
- Sensory Loss
- Urinary Incontinence
Three Weeks After Regenerative Cell Therapy

21-year-old-male

After
- Bilateral lower extremity muscle strength: 3
- Tactile and proprioceptive sensation restored
- Urinary and stool incontinence partly improved
- Walks on crutches or with assistance
Bilateral Thalamic Hemorrhage

53-year-old-female

Before

- Unconscious
- Unable to move limbs
- Vegetative
Four Weeks After Regenerative Stem Cell Therapy

53-year-old female

After

- Consciousness
- Language function
- Communication skills
- Regained partial motor functions
Pulmonary Embolism

38-year-old male

Before

- Hypoxic-ischemic encephalopathy caused by pulmonary embolism
- High muscle tension
- Movement disorders
- Resting tremor
- Irritable
- Aphasic
Pulmonary Embolism

38-year-old male

Three Weeks After
- Walk 200 m without assistance
- Absence of resting tremor
- Significantly reduced irritability
- Able to pronounce simple words
- Partial Recovery of emotional expression

Twelve Months After
- Complete recovery of sensory, motor and language functions, emotional expression and intelligence
Type 2 Diabetes Reversal

56-year-old female

Before

- Poorly controlled for eight years
- Complicated with bilateral plantar ulcers
### Improved Blood Glucose Control

**56-year-old female**

<table>
<thead>
<tr>
<th></th>
<th>Before</th>
<th>1 Week After</th>
<th>3 Weeks After</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pre-prandial</td>
<td>27.5</td>
<td>12.5</td>
<td>6.5</td>
</tr>
<tr>
<td>Post-prandial</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2h after breakfast</td>
<td>30.6</td>
<td>15.6</td>
<td>10.6</td>
</tr>
<tr>
<td>2h after lunch</td>
<td>26.9</td>
<td>11.9</td>
<td>8.9</td>
</tr>
<tr>
<td>2h after dinner</td>
<td>27.8</td>
<td>10.8</td>
<td>8.8</td>
</tr>
</tbody>
</table>

**Note:** Numerical value indicates plasma glucose level in mmol/L
Wilson Disease

Brothers

27-year-old male
22-year-old male

Before
- Hand tremor
- Ataxia (lack of coordination)
- Dystonia (twisting and repetitive movements of part of the body)
- Migraine
- Apathy
- Executive dysfunction with poor planning and decision making
- Depression, anxiety

One month after stem cell treatment
- Increased energy level
- Improvement in their ability to control hand tremor
- Improvement in behavioral health
- Improvement in coordination and motor skills
Wilson Disease
Our Results

- High Quality: over 90% of spinal cord injury patients in our stem cell treatment group reported improvement

- Low Cost: we are a trim organization with low overhead

- Dramatic increase in brain function and motor skills in traumatic head injury patients

- Safety and Efficacy study in US: 50+ treatments with no adverse reactions
Safety Study of Intravenously Administered Human Cord Blood Stem Cells in the Treatment of Symptoms Related to Chronic Inflammation
## Changes in indicators associated with chronic inflammation and anti-aging

<table>
<thead>
<tr>
<th>Parameters</th>
<th>24 hours after treatment</th>
<th>2 weeks after treatment</th>
<th>3 months after treatment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Increased energy level</td>
<td>33,3±16,7%</td>
<td>55,5%±17,6%</td>
<td>66,7%±16,7%</td>
</tr>
<tr>
<td>Hair and nails grow faster</td>
<td>-</td>
<td>11,1%±11,1%</td>
<td>44,4%±17,6%</td>
</tr>
<tr>
<td>Improved skin</td>
<td>-</td>
<td>11,1%±11,1%</td>
<td>44,4%±17,6%</td>
</tr>
</tbody>
</table>
Improvement in energy level, hair, nails growth and skin condition following stem cell treatment

- Increased energy level
- Hair and nails grow faster
- Improved skin
THANK YOU!

"Stem cell treatments are without a doubt the future of medicine…"

Dr. Brian Mehling. PR Newswire: Biotechnology, November 2013