

## **BREAKING NEWS!!!**

### **Crolles, February 2018**

In 2018, Association NEURO-GEL En Marche in partnership with THE INTERNATIONAL SPINAL CORD INJURY TREATMENT CENTER, at the Tongren Hospital in Kunming, China has plans underway to conduct a series of operations for treatment of chronic lesions of the spinal cord using activated fat--a three-dimensional autologous matrix derived from adipose tissue combined with erythropoietin (EPO),

### **FUNDING A 12 PATIENT STUDY.**

Association Neuro-Gel en Marche must bear the financial cost for the study and launched a fundraiser with the goal of obtaining funds to cover the costs associated with treating a minimum of 12 volunteer patients: 6 American or French patients and 6 Chinese patients. Volunteers can leave their contact information at \_\_\_\_\_ web site.

A reliable estimate of the cost for 12 patients in China has been quantified with the Tongren hospital. The total cost of operations with a one month hospital/clinic stay, including surgery, 11 months of physiotherapy in China, all related medications (including EPO) and quarterly analyses (Kunming scale, scanner, MRI, radios, etc.) is 720,000 euros for 12 patients.

This cost includes stay in a private ("luxury") room. Some patients may require unique nursing assistance. This and meals are the responsibility of the patient.

Currently, the Association, with the help of various donors, has raised 350,000 euros: half of the required sum.

In anticipation that full funding will be obtained, the Association is now recruiting volunteers willing to undergo surgery, followed by a year of rehabilitation at the Kunming Hospital in the Yunan province of China.

The Kunming Hospital is an international center for the treatment of spinal cord injury that has performed over 5,000 operations on chronic and acute spinal cord lesions with different therapeutic pathways such as Schwann cells, adipose tissue derived stem cells, mononuclear cells from umbilical cord, accomplished with or without lithium.

The team of Drs. Zhu and Liu, who will accomplish the surgeries and strictly monitor rehabilitation protocols, regularly accomplishes a surgical protocol developed by the late Dr.

Antonio Reis for implantation of an activated fat composition using EPO developed by Professor Gorio at the University of Milan.

The surgical protocol has proven crucial to release the spinal cord from the stresses associated with various pressures caused by fibrosis, arachnoid cysts, dura mater attached to the vertebrae, poorly fitted vertebrae, cavities syringomyelic.

As a result, perfect circulation of the cerebrospinal fluid, to rebuild conduit to the brain occurs and whenever possible, restores the rachis, removes the adhesions, the cysts and removes the necrotic tissue or tissues so that the medullary cord may no longer undergo any vascular constraint. Essentially becoming like a guitar string, free of any movement!

**The Kunming Tongren Hospital has decided to use the activated fat obtained from the patient's adipose tissue, combined with Erythropoietin (EPO).**

Previously, Dr. Liu's team of neurosurgeons used stem cells derived from the patient's adipose tissue to fill the cavity present after surgically exposing the spinal cord then after being perfectly curretted, the spinal cord is given an anatomical dimension again.

However these stem cells had limited survival capability; they did not necessarily remain on the lesion site and they did not have the ability to promote true tissue regeneration. The results were mixed despite some signs of recovery.

Upon reviewing Professor Gorio's research results, Doctors Zhu and Liu quickly understood the importance of the activated fat and EPO. This three-dimensional bio-adhesive autologous matrix has not undergone any genetic or enzymatic modification and contains stem cells with strong survival and cell regeneration power.

Unlike artificial biomaterials such as hydrogels, activated fat from adipose tissue is not fragile. It is easy to use and the implantation adjusts to fill the cavity occurring after removing all shapes of lesions from the spinal cord.

The extremely high levels of immunosuppressive, anti-inflammatory factors, and numerous cell growth factors have convinced Drs. Zhu and Liu that the stem cells will be able to attract and recruit the endogenous neural stem cells from within the activated fat to form and reorganize new and functional spinal cord tissue.

Professor Gorio has provided all available data on EPO and its key role in the organization of this neural regeneration in adults. This combined medication to be administered for a period of thirty days is described in the operating protocol (located on this web site).

**TONGREN HOSPITAL PHYSICAL REHAB CENTER**

**The hospital has an intensive physical rehabilitation center.** Physiotherapy is an essential element of this study and patients must accomplish the rehabilitation protocol for at least 12 months. This is because post-surgery, rigorous rehabilitation is required to accomplish significant functional re-education to allow the nerve fibers to form synapses and reach neural targets. As such, it is necessary to stimulate the sub-lesional pathway through physiotherapy.

Dr. Zhu's team has a very precise protocol of 36 hours of rehabilitation per week with walking, mobilization, acupuncture, stand-up, ground exercises, low frequency electro stimulation and physiotherapy.

The progress assessment is based on the Kunming scale, a program developed by Dr. Zhu. Patients stay at the International Center and will benefit from all the necessary nursing care.

### **VOLUNTARY PATIENT INCLUSION CRITERIA.**

- Voluntary patients should be aware that the surgical procedure will represent only part of the regeneration process. Surgery alone will not produce healing.
- Patients will have to agree to undergo intensive therapy of at least one year at the physical rehabilitation center of the Tongren Hospital in Kunming, China or possibly at the Step by Step Center in Barcelona (in this case, at their own expense).
- Before signing up, patients should consider the long-term implications and should be prepared, if need be, to devote themselves to years of rehabilitation.
- The patient must have a complete motor and sensory deficit. Score ASIA A = no traction or sensitivity in the Territory S4-S5
- The age of the patient should be between 20 and 55 years.
- No restriction as to the age of the lesion
- No restriction on the size and/or number of lesions
- Complete or incomplete paresis
- Incomplete lesion
- Lesion between C5 and T11

### **EXCLUSION CRITERIA**

- - The level of injury limited to C5 for quadriplegics
- - Minor Patient and under 20 years of age
- - Diabetes

- - Hepatitis B or C Infection
- - Acquired immunodeficiency syndrome
- Tendon restriction and inability to maintain a vertical station.

If you meet the criteria listed above and your application is accepted by the neurosurgeon, please contact the President or Vice-President of the Association at \_\_\_\_\_.

**To complete their application, volunteer patients will have to undergo a series of tests including and provide the following to the medical team:**

- MRI of the lesion
- MRI of thigh and calf muscles
- Spinal Xray and/or scan
- Electromyography of muscles and peripheral nerves
- Somatosensory Tests (Evoked Motor and Sensory Potentials)
- Rorschach's, Rozenzweig's and Raven's psychological tests, and the Minnesota Multiphasic Personality Inventory.
- Bloodwork and urine analysis

The completion of these tests can take 2-3 months depending on the availability of hospitals and doctors.

The patient will have to sign an informed consent form in which a summary of the procedure and the risks involved will be clearly defined. The patient will also have to undergo a series of tests during the year following the surgery, as well as enroll in a predetermined physiotherapy protocol, the Kunming scale.

The patient will remain anonymous but will have to accept the disclosure of the personal data collected for a possible medical publication.

The risks are minimal because the activated fat is an autologous tissue ( belonging to the patient) taken at the abdominal level, without chemical or genetic modification, and that has never caused rejection, mutagenicity, and inflammation.

The cytokine called erythropoietin used in the therapy is well-known and well-controlled.

## **SURGICAL RISKS**

Patients will be required to sign a more detailed consent form identifying all risks. They include:

- Medical complications after anesthesia, including death.
- Infections due to the neurosurgical aspect of surgery, such as meningitis, myelitis
- The neurological symptoms may worsen after the procedure due to the presence of debris and the implantation of the activated fat. Note that this risk is higher in patients with cervical lesions.
- -Injury caused by post-operative swelling of the spinal cord, which may result in a higher level of injury.
- Secondary Syringomyelia in the segment of the spinal cord, as a late complication
- Other post-operative complications include post-operative complications such as pneumonia, deep vein thrombosis, scarring and urinary tract infections.

## **VOLUNTEER PATIENT CONTACT INFORMATION**

Potential volunteers can leave their contact information at \_\_\_\_\_ (web site?). Any information provided will be handles with the strictest confidentiality.