

*NeuroGen Guide on*  
**Neuro Regenerative  
Rehabilitation Therapy**  
*(including stem cell therapy)*  
*For incurable neurological diseases*



**NeuroGen**  
Brain and Spine Institute  
ISO 9001:2008 Certified

## About NeuroGen Brain and Spine Institute

Diseases and injury of the brain and spinal cord produce damage to the nervous system with resultant paralysis/ weakness of limbs, speech / visual & other neurological symptoms. For many such conditions proven interventions do not exist or have been ineffective therefore these patients continue to be symptomatic and suffer severe physical and neurological disability despite all possible medical, surgical and rehabilitation assistance.

The NeuroGen Brain & Spine Institute has been set up to help such patients get relief from their symptoms and physical disabilities using the safest and most effective available treatments and technologies from the field of the Neurosciences & Regenerative medicine in a professional & scientific as well as a holistic & caring manner.



Our strategy is to promote the recovery of neural function with a close integration of Neuro-regenerative (stem cell), Neuro-protective (medications) and Neuro-rehabilitative (physical/occupational/speech) therapies. This therefore combines the best of Neurobiological repair technologies and Neural restorative techniques. We recognize that even small functional gains may have a significant effect on the quality of life of our patients. Our treatment is individualized to the specific requirements of each patient.

The NeuroGen medical panel includes:-

- 1) A Medical team (Neurosurgeon, Neurophysician, Pediatric Neurologist, Psychiatrist, Urologist, Andrologist, General physician, General Surgeon, Orthopedic surgeon & Ophthalmologist),
- 2) A Basic Science team (Neuropathologist, Microbiologist & Geneticist) and
- 3) A Rehabilitation team (Physiotherapist, Occupational therapist, Speech therapist & Psychologist)

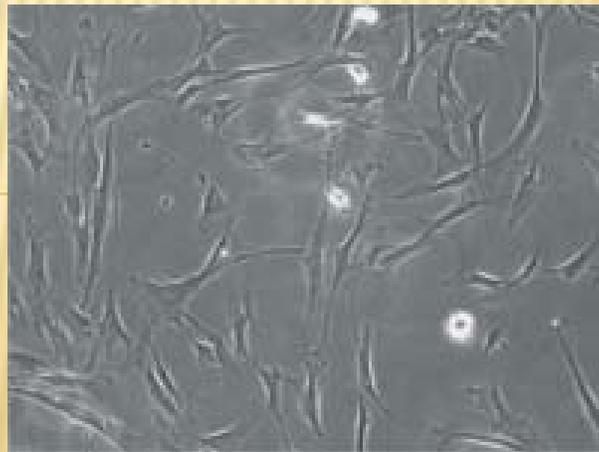
In addition to medical treatment there is a significant emphasis on both clinical as well as basic research so that the best therapeutic strategies can be evolved and practiced at the same time.



## What are Stem cells ?

Stem cells are essentially the building blocks of the human body. All of us have originated from stem cells. In our mothers womb, we are initially a group of stem cells which are known as embryonic stem cells. As these multiply and grow, the entire human body is formed in 9 months .At the time of birth some stem cells are present in the umbilical cord that connects the mother and the baby and these are referred to as umbilical stem cells. After birth some of the stem cells are still active in the process of producing new cells, such as blood, which are referred to as adult stem cells.

The primary properties of stem cells that make them a useful form of therapy are that (1) stem cells have the potential to convert into any type of body cells as well as the ability to multiply into larger numbers (2) they can be easily isolated, separated & grown in the laboratory (3) they have a natural tendency to repair and regenerate damaged parts of the body.



## **Types of stem cells are:**

### **i. Embryonic Stem Cell(ESC)s:**

Embryonic stem cells are derived from embryos obtained from IVF clinics and aborted tissues. They are ethically controversial since their use involves destruction of the embryos and since there is the potential danger of tumor formation. The ICMR puts the use of these cells in the restrictive category. At NeuroGen we do not use embryonic stem cells.

### **ii. Cord Blood Stem Cells:**

These are obtained from the umbilical cords at birth and they are collected and stored in cord stem cell banks which have been set up by some large corporations. The ICMR puts the use of these cells in the permissive category.

### **iii. Adult stem cells:**

These stem cells are found in adult tissues, such as bone marrow. Their primary role in the body is maintenance and repair of different tissues. These adult stem cells have the potential to form other types of tissues such as neurons. The ICMR puts the use of these cells in the permissive category. The advantage of using adult stem cells is that recipients will not experience immune rejection or any other serious side effects since it is their own tissue (autologous) that is being injected back into them. Also, since these are easy to obtain through a simple bone marrow aspiration, the patient has to undergo only a very simple procedure which can be done under local anesthesia. At NeuroGen we focus on the use of adult stem cells due to their safety and efficacy.

## Disorders considered for NRRT

### A. Spinal Cord Injuries.

### B. Incurable Neurological Diseases:

- Muscular dystrophy
- Multiple Sclerosis
- Brain stroke
- Cerebral Palsy
- Dementia
- Autism
- Motor neuron disease
- Sequelae of head injury.
- Sequelae of neurological infections.
- Genetic neurological disorders.



## NRRT treatment Schedule:

The total hospitalization period is 6 days. Extended stay options for longer rehabilitation are also available. The complete treatment involves Regenerative medicine (using Adult stem cells), Neurological and other medical treatments (using Neuroprotective and other medications) and Rehabilitation (including physiotherapy, occupational therapy, speech therapy, counseling, creative visualization etc). All the complaints, problems, symptoms of the patient are attended to by appropriate consultants and suitable treatments are initiated. Our comprehensive treatment involves a holistic approach towards the total well being of the patient, which through an improvement in their neurological condition, helps in improving the quality of their lives.

DAY 1	DAY 2	DAY 3 - 6	DAY 6
EVALUATION	STEM CELL THERAPY	REHAB	DISCHARGE
<ul style="list-style-type: none"> <li>• Complete Patient evaluation by different consultants</li> <li>• Investigations</li> <li>• Surgery procedure explanation</li> <li>• Signing the special informed consent forms</li> <li>• Preanaesthetic assessment</li> </ul>	<ul style="list-style-type: none"> <li>• Stem cell therapy is done only once during this 6 days stay. It consists of the following parts:</li> <li>• Aspiration of Bone marrow (~1/2 hr in the OT)</li> <li>• Separation of Stem cells (~ 2-3 hrs in the lab)</li> <li>• Injection of the isolated Stem cells. (~1/2 hr in the OT)</li> </ul> <p><i>(The bone marrow aspiration and injection are done under local anesthesia and mild sedation in adults. Small children may require general anesthesia.)</i></p>	<ul style="list-style-type: none"> <li>• Physiotherapy.</li> <li>• Occupational therapy</li> <li>• Speech therapy</li> <li>• Patient Counseling</li> <li>• Family counseling</li> <li>• Creative Visualization.</li> <li>• Medical management of spasticity, Pain, urinary and bowel problems, sexual dysfunction and pressure sores and other related problems</li> </ul>	<ul style="list-style-type: none"> <li>• Post treatment evaluation.</li> <li>• Discharge</li> </ul>

## Most Frequently Asked Questions:

### *How does stem cell therapy work?*

The biological task of stem cells is to repair and regenerate damaged cells. Stem cell therapy exploits this function by administering these cells in high concentrations directly in and around the damaged tissue, where they advance its self-healing and repair.

### *Are there ethical concerns surrounding adult stem cell research and therapy?*

Bone marrow transplantation has been used successfully for genetic disorders of blood, such as sickle cell anemia, thalassemia, as well as cancers such as leukemia. Since our therapy uses these very cells, which are harvested from the patient's own body (autologous cells), there are no major ethical concerns. Ethical concerns are primarily on the use of embryonic stem cells (which we do not use).

### *Before Surgery :*

#### *If I go for the treatment, are there chances of me getting in a worse condition?*

No. We have not observed any neurological deterioration in any of our patients due to the stem cell therapy per se. However, it is important to keep in mind, that certain neurological disease, e.g. MND, have a natural course of progress, which may continue despite the stem cell therapy. Patients with pre-existing medical problems such as diabetes, hypertension, cardiac, respiratory, renal or hepatic problems may have a possibility of deterioration.

#### *Is any special diet required?*

No.

*What examinations and investigations are to be performed before the therapy?*

**A) The basic routine tests (for all patients) :**

- CBC , Blood sugar (fasting/PP), S Creatinine, S Electrolytes , LFT , CT, BT, PT , HIV I and II antibodies, HbsAg, HCV antibodies,
- Urine routine ,
- ECG,
- X Ray chest (PA view)

**B) Some special tests will have to be done in addition depending on the disease/ injury, age of patient and associated medical problems.**

- S CPK (Total and MB)
- Genetic testing
- ABG
- EMG NCV.
- SSEP
- EEG
- VEP
- MRI Brain with screening of spine
- MRI Brain
- MRI spine
- MRI (Musculoskeletal system) upper limbs and lower limbs
- PET CT SCAN (Brain)
- 2D ECHO heart
- PFT
- Venous Doppler(both lower limbs)
- USG (KUB)
- Urodynamic studies

## *During Surgery:*

### *Is the treatment painful?*

The therapy is done under local anesthesia and a mild sedation. There is no significant pain or discomfort during or after the procedure.

## *After Surgery:*

### *When do I go home?*

On the sixth day by evening. (You would be handed over the discharge summary along with an exercise DVD) . An extended stay option for rehabilitation therapy is also available.

### *Does the treatment have any side effects?*

Stem cell therapy is minimally invasive and reasonably safe. None of our patients have shown any neurological deterioration so far in connection with the stem cell therapy itself. Some side effects, such as a headache (spinal headache) lasting 3-4 days which is generally self limiting, neck / back pain, vomiting, some mild rash or pain at the site of bone marrow aspiration/stem cell injection may occur. However, like any other medical or surgical treatment unexpected complications are always a possibility. These complications may be related to the medicines given, the stem cell procedure, the anesthesia, the rehabilitation or to any of the preexisting medical or neurological conditions.

### *How much improvement will the patient have?*

This is difficult to predict, since this is a new therapy. It depends on multiple factors such as the age of patient, type of illness, duration of illness and the extent of rehabilitation taken after the treatment. It is important to note that at NeuoGen we give no assurances or guarantees of any definitive improvements

or results. However our past clinical results are available on our website as well as in various medical and scientific publications. You are strongly advised to study these before proceeding with the treatment. The staff at NeuroGen would be happy to provide you with additional detailed information in this connection.

***How long will it take me to know that I have benefited from the treatment?***

Maximal improvements are seen around 2-3 months after the treatment. However in many patients there are slow progressive improvements that continue for several months/years later. Most patients do show some immediate improvements also, i.e. before the discharge, in some of their symptoms.

***Is the transplantation of the stem cells done once or more than once?***

The decision to do the therapy a second time is taken after seeing the progress/improvements after the first therapy. If the patients show some encouraging improvement, then the case is reviewed by the entire medical and rehabilitation team and a second treatment may be recommended. This may be done anytime between 2-6 months of the first therapy.

***Can other treatments be taken at the same time?***

We will review what other medications the patient is already on. In most cases we do not discontinue any already going on treatment. However this is decided on a case by case basis.

## Check-list Pre-Admission

This check-list will help you prepare for your surgery. Check each item to avoid cancellation or unnecessary delays.

- ❑ An injection has to be given 2 days before the admission. This is Inj. G-CSF (XPHIL/Grafeel/Neukine) 1cc subcutaneously. Doctors from NeuroGen will give you a prescription for the same. This injection can be given to by your local family doctor.
- ❑ Arrival time to the hospital on day one is between 9 am and 12 noon. However if you are from out of town and your arrival depends on your flight/train timings please keep the staff at NeuroGen informed so that necessary arrangements can be made. Ambulance transportation from the airport/ station to NeuroGen are available at request.
- ❑ Lab tests consisting of blood and urine investigations, MRI EMG etc have to be done a week in advance and these reports have to be communicated via telephone or e mail to the Head of medical services.
- ❑ If you fall ill or have fever, cough/cold or respiratory problems call the doctors at NeuroGen. The doctor will decide if it's safe to proceed with the treatment.
- ❑ If you have any medical/surgical condition, for example:- Hypertension, Diabetes, Respiratory problems (breathing difficulty), Cardiac problems (Chest pain), Renal (kidney) problem, Urine infection, bedsores etc please inform us before so that appropriate investigations can be done.

- ❑ Patients on anti-coagulant/ anti-platelet treatment should also inform us before.
- ❑ Please note that our anesthetist will evaluate you on the day of admission and for any reason if it is felt that you are not fit to undergo the treatment, then the treatment may be postponed or cancelled. If this is done it is purely keeping the patient safety in mind.



## Follow-Up Care

It has been observed that patients who have continued a regular, vigorous and intensive rehabilitation program after the therapy have shown better and sustained clinical improvements. Hence, it is advised to follow the International rule of 6 which says “**6 hours** of rehabilitation activities per day for **6 days** a week for **6 months**”.

We are happy to communicate with your therapists (telephonically as well as via mail) as to what special therapy you need. We also give you a DVD of all the rehabilitation you have undergone at NeuroGen so that your personal therapist can get a better understanding of your post treatment rehabilitation needs.

Follow-Up visits to NeuroGen need to be made at one, three, six months and one year post stem cell therapy when you will be evaluated to check for the improvements. Some investigations such as EMG/NCV, PET CTScan, MRI etc may have to be repeated during this follow-up period. For patients who stay outside Mumbai the follow-up dates are suitably modified depending on your ability to travel to Mumbai. All follow-ups are to be done with prior appointments only.



## Disclaimer

- ❖ The ethical guidelines followed by NeuroGen are based on & are in accordance with the World Medical Association's "WMA Declaration of Helsinki - Ethical Principles for Medical Research Involving Human Subjects " - paragraph 35 (a synopsis of which is "In the treatment of a patient, where proven interventions do not exist or have been ineffective, the physician, may use an unproven intervention if in the physician's judgement it offers hope of saving life, re-establishing health or alleviating suffering. " The complete details are available at :-<http://www.wma.net/en/30publications/10policies/b3/index.html>
- ❖ At NeuroGen ,we do not claim to cure any of the neurological diseases. Our treatment strategy, techniques and goals focus on giving patients functional improvements to improve the quality of their lives.
- ❖ In accordance with the ICMR guidelines, an Institutional Committee for Stem Cell Research & Therapy (IC-SCRT), has been formed, which evaluates, approves and monitors all the clinical work, data and research work done at NeuroGen.
- ❖ There are differences in nomenclature/ terminology with regard to the cells used for transplantation. Different doctors/ researchers in different countries refer to the cells in different ways. We are presently transplanting mononuclear cells derived from the patient's own bone marrow for the cell transplantation therapy. Similar cells from umbilical cord are also available. These are also referred to as "stem cells", "adult stem cells", "stem cell like cells", "haemopoetic stem cells", "mesenchymal stem cells" etc etc
- ❖ Prior to the treatment special informed consent is taken both for the treatment as well as for your participation in the clinical study/trial that you may be a part of. This consent has been framed in accordance with ICMR guidelines and certain relevant judgments of the Supreme court of India. This Process is videotaped and it is very important that the patient and family members understand all aspects of this.
- ❖ There are some controversial issues involved with stem cell therapy, its indications and the regulations that govern its use. Not all doctors / organizations agree with many of the issues. These issues are connected with the type of stem cells used, the methods of transplanting them and the current evidence that exists about the the possible risks and efficacy. We recommend that you consult your treating doctor and seek his/her advice before undergoing the therapy.

*This information is basic and elemental for patient familiarization only.  
This information is not a substitute for medical advice.*

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