

## **ASSI POSITION STATEMENT ON STEM CELL AND OTHER CELLULAR INTERVENTIONS AFTER SCI**

Spinal cord injury is one of the most devastating ailments which can afflict mankind! Complete injuries leave the person paralyzed below the level of injury. In tetraplegics all four limbs and torso are paralyzed whereas in paraplegics both lower limbs and torso below the level of injury are paralyzed. Such injuries have serious medical, psychosocial and economic consequences on not only the individual but also the whole family. Since neurons are not able to regenerate effectively for functional improvement, complete injuries do not generally recover neurologically. The treatment goal is to rehabilitate them comprehensively so that they can lead a happy and meaningful life from their wheelchair. Since the prognosis for neurological recovery in complete spinal cord injuries is poor, the spinal cord injured and their families look forward to any treatment which could help them to recover and they are often desperate in this regard.

Pre-clinical and clinical studies have revealed that stem cell and cellular transplantation hold a good promise and potential. In fact some forms of stem cell transplantations have been successfully used to treat some blood and immunological disorders. There has also been a lot of excitement about the potential of stem cell and cellular based interventions for spinal cord injuries. Many studies performed involving animal models of spinal cord injury (mostly rats and mice) have shown a good potential for such interventions. However, animal studies have a lot of limitations especially since they do not exactly mirror SCI in humans. Thus, it is important to conduct valid clinical trials to evaluate whether stem cell and cellular transplants can be offered as a valid option after SCI. Some properly conducted clinical trials are now being undertaken, but it is advisable to wait for the results from these objective studies.

There has been no established evidence to-date that stem cell and cellular transplants are successful for management of human spinal cord injuries. There is however evidence that there are significant safety risks associated with such transplants. Further more people with spinal cord injury can get back to a normal lifestyle with proper conventional medical care and rehabilitation training. In view of this, it is advisable that spinal cord injured and their families make informed decisions regarding the plethora of so called “effective” stem cell and cellular transplants being offered across the world, typically for large sums of money. They should not get influenced just by patient testimonials. These cannot be relied upon because of the possibility of biases by many confounding factors like placebo effect and natural history of the disease.

As per the latest National guidelines for stem cell research published by ICMR and DBT “*any stem cell use in patients must only be done within the purview of an approved and monitored clinical trial with the intent to advance science and medicine, and not offering it as therapy. In accordance with this stringent definition, every use of stem cells in patients outside an approved clinical trial shall be considered as malpractice.*”

ASSI endorses the National Guidelines on stem cell research (<http://icmr.nic.in/guidelines/NGSCR%202013.pdf>) and Guidelines for the Clinical Translation of Stem Cells by the International Society for Stem Cell Research (<http://www.isscr.org/home/publications/ClinTransGuide>). While ASSI acknowledges the possibility that in future stem cell and other cellular based interventions may be accepted as a valid choice of therapy after SCI, the evidence base for the same must come from a valid clinical-trial program. Currently, it is unethical to offer experimental interventions that are not yet proven to be safe or effective and more so to charge patients for this. International Spinal Cord Society (ISCoS) also voices similar sentiments in their position statement (<http://www.iscos.org.uk/statement-on-stem-cell-therapy>).

More information on stem cell and cellular transplants and questions that should be asked of someone offering a treatment for SCI is available in the following sites

- <http://www.cdscsco.nic.in/writereaddata/DRAFT%20GUIDANCE%20STEM%20CELLS-FINAL.pdf>
- <http://www.closerlookatstemcells.org/>
- ‘Experimental Treatments for Spinal Cord Injury: What you should know’ <http://www.campaignforcure.org/>
- <http://www.isscr.org/home/publications/patient-handbook>