Spinal Cord Injury

Stem cells will eventually be used to treat stroke and spinal cord injury patients. In fact, those conditions come immediately to mind when the new field of "regenerative medicine" is mentioned. Therefore, an announcement that the FDA has approved the first clinical trial involving embryonic stem cells (ESC) caused considerable excitement. However, this announcement also serves as a reminder of the many hurdles that must be overcome and how long it may take before such stem cell treatments are safe and effective.

The pharmaceutical company, Geron, collaborated with the University of California, Irvine to develop this line of "oigodendrocyte progenitor cells" that will be used in this study. The cells have the ability to turn into "glial" cells that normally provide a coating for nerves. It may be helpful to imagine nerves as electric wires and glial cells as providing the insulation. The scientists have shown that similar cell lines reduce the severity of spinal cord injury when injected into rats, and they hope the same will be true in patients.

There are several important things to understand about this approach. As a Phase I clinical trial, the main goal is to establish safety. If the cells are not handled in exactly the right way, it is possible they could cause cancer when injected into patients. The treatment must be done within 7-14 days of the injury and will not replace damaged nerves, just their "insulation". Animal experiments suggest that the injected cells will provide a better environment for healing, but there are no guarantees that will be the case in humans.

The oligodendrocyte progenitor cells are grown in cultures of ESC that were originally obtained from an *in vitro* fertilization clinic. A fertilized egg that could have been implanted in a uterus was instead used to produce the ESC line. This tiny ball of cells had never been inside the body and would have been kept indefinitely in a freezer or destroyed. However, a substantial number of people object to use of embryonic tissues for research and treatments. For that and scientific reasons, OCASCR is excited about procedures that are being developed for making stem cell lines from adults.

In order to do this treatment quickly, the oligodendrocytes have to be prepared in advance and will not be genetically matched with the patient being treated. It is possible that the immune system will reject them. Therefore, all of the patients in this type of clinical trial will be given immunosuppressive drugs. It would be an advantage if stem cells could be tailor made from the patient's own cells, and especially if it could be done rapidly. That is the goal of one Oklahoma research project being supported by OCASCR.

It has been estimated that there are over a million patients in the US with some type of spinal cord injury and it is understandable that many are frustrated by conventional medical research. Properly conducted clinical trials are very expensive and time consuming, but necessary to insure patient safety and effectiveness.

Clinics around the world announce that they can "cure" spinal cord injuries with stem cells, scoffing at the pace of research and clinical trials in the US. Many desperate patients grasp at the hope offered by these clinics, and it is never possible to say there is absolutely no chance of success. However, patients should be very wary of physicians who do not fully disclose their methods and who base their claims on testimonials rather than research results. Currently we are unaware of any effective stem cell treatments for spinal cord injury that have a sound scientific basis. If the results of this study are promising, Geron plans to try treating patients with Alzheimer's disease and multiple sclerosis.