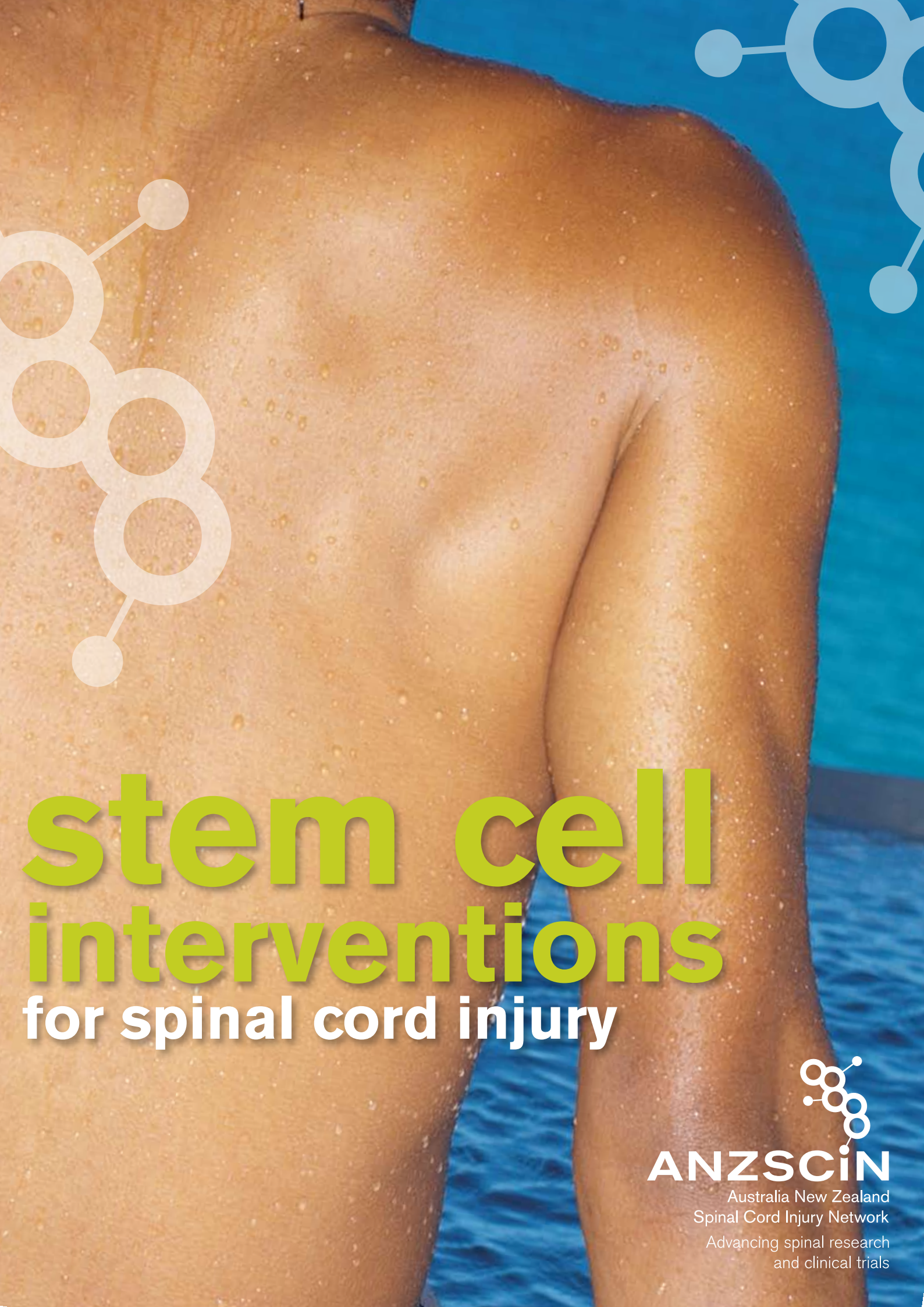


stem cell interventions for spinal cord injury

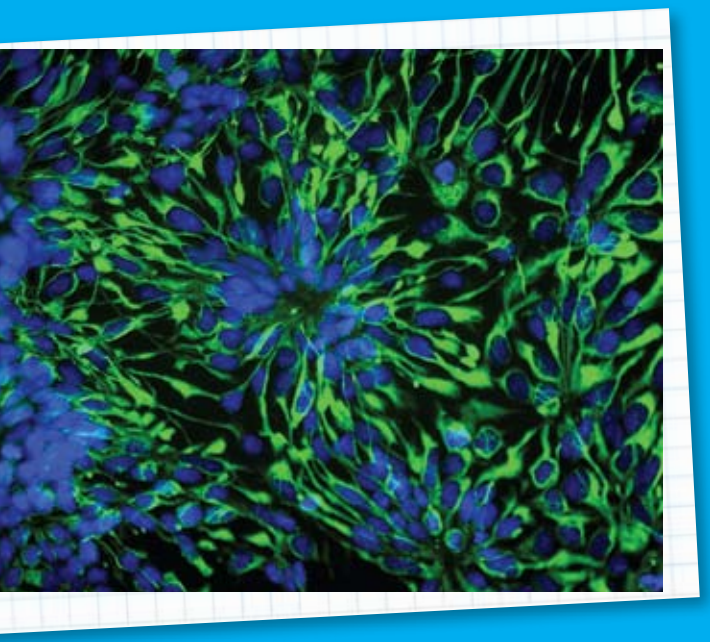
ANZSCiN

Australia New Zealand
Spinal Cord Injury Network

Advancing spinal research
and clinical trials

Stem cell interventions for spinal cord injury

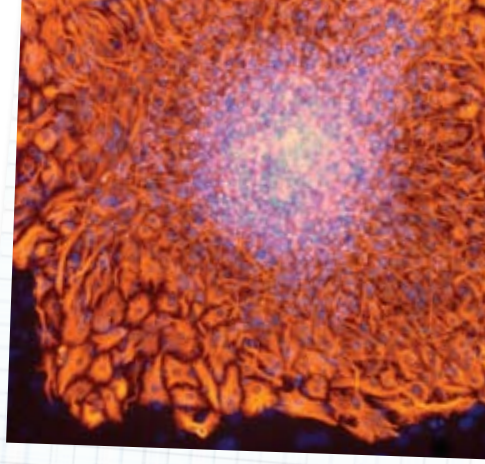
Stem cell research is in its relatively early stages. While laboratory and animal research to date holds great promise for treating a range of illnesses in the future, there are currently no stem cell therapies that are recommended for people with spinal cord injuries. Translation of laboratory-based stem cell research into treatments is likely to take many years and must be conducted with strict oversight. This includes ethical safeguards to protect the welfare of the patient and respect for the moral status of the embryo used in embryonic stem cell research.



There are some stem cell research programs underway that may eventually lead to promising treatments for spinal cord injury, but none of these have been completed and confirmed yet. There is growing concern that stem cell therapies are being sold around the world before they have been proven safe and effective. The controversial treatments that have been offered in some parts of China, India and other countries have not been reported in respectable peer-reviewed scientific journals and have not been replicated by other scientific groups. The researchers providing these treatments only highlight the positive outcomes, have no, or very limited, pre- and post-treatment assessments, and often charge money to vulnerable individuals. Reports rely on testimonials from people who say that they have had improvement. We rarely hear about the people who have not improved. We know little about the possible side-effects and long-term complications related to these procedures. Some serious side effects including meningitis and death have been reported. Unethical and poor scientific practices as described above could in fact hinder the advancement of this important area of research.

In summary, people with spinal cord injury should be extremely careful at this stage about participating in experimental procedures which are expensive, and which have not been proven to be safe and effective. Individuals should be well informed about what is involved in experimental stem cell procedures and any side-effects of such treatments.

Seek advice from your spinal cord injury unit or specialist if you are considering participating in these types of stem cell procedures or any other research trials.



Frequently asked questions (FAQ's)

What are stem cells?

Stem cells are unspecialised cells that can repair damaged body tissues. They are found in the early embryo and foetus, the placenta and umbilical cord, as well as in adult tissues and organs throughout the body. Stem cells have been shown to reproduce themselves through cell division and under certain conditions can give rise to specialised cells.

Embryonic stem (ES) cells

ES cells are produced from a 4-7 day old embryo called a blastocyst. Cells are removed from the embryo and grown in the laboratory. The embryos from which these cells are derived are "left over" fertility clinic (IVF) embryos that would otherwise be discarded and are obtained only with the donor's informed consent. The cells are not from naturally conceived embryos. Embryos cannot be specifically created for research purposes. These ES cells cannot produce a human being but can give rise to any cell type or tissue in the body.

The advantages of ES cells are that large numbers can be grown in the laboratory relatively easily and that they are good at dividing and renewing themselves. They are sometimes referred to as immortal. The disadvantages of these cells are that, in some circumstances, they may form tumours and may trigger immune rejection after they are transplanted into tissue.

Embryonic stem cell research has been legal under strict conditions in Australia since 2002 (please see link to legislation at the end of this section).

Adult stem cells

Adult stem cells are produced from body tissues, including tissues from babies, children and adults, as well as from discarded umbilical cords and placentas. These cells have the potential to make cells of their own type but usually not other types of cells. Their main job in a living organism is to maintain and repair the tissue in which they are found. They have now been found in many more tissues than once thought possible, including the brain.

Adult stem cells are less controversial than ES cells because there is no destruction of embryos. Problems with immune rejection can be avoided because they are produced from the patient's own cells. The disadvantages of these cells are that there are only very small numbers of these stem cells in each tissue and it is difficult to grow a large number of them in the laboratory. They are more specialised than ES cells and therefore have limited ability to produce different cell types and to self-renew. Another possible disadvantage is that adult stem cells are as old as the body from which they are taken and their genetic material may be damaged.

New research has shown that some adult stem cells may be able to make cell types of a completely different tissue (under some experimental conditions), which is known as plasticity. An example of this is stem cells derived from blood (hematopoietic stem cells) directed to become brain cells (astrocytes, oligodendrocytes and neurons).

Embryonic germ stem cells

Embryonic germ stem cells are produced from the part of a human embryo or foetus that will ultimately produce eggs or sperm. Not much research is being performed with these types of cells since they do not appear to be as versatile as ES cells and do not live for very long. They are also controversial because they make use of embryos or foetuses from terminated pregnancies.

Induced pluripotent stem (iPS) cells

iPS cells can be produced from any specialised cell in the body, for example a skin cell. Like ES cells they can be turned into any cell type. iPS cells are patient-specific and thus avoid problems related to immune rejection. It is still unclear how stable or safe they would be for clinical use.

More information on stem cells –

- Australian Stem Cell Centre
  www.stemcellcentre.edu.au/public-education_fact-sheets.aspx
- National Institutes of Health – follow-link "Learn more about stem cells"
  www.stemcells.nih.gov
- Stem Cell Ethics
  www.stemcells.ca
- Embryonic Stem Cell Legislation – Australian Government, Attorney-General's Department
  www.comlaw.gov.au/comlaw/management.nsf/lookupindexpagesbyid/IP200401880?OpenDocument

What is therapeutic cloning?

Therapeutic cloning or somatic cell nuclear transfer (SCNT) is where "patient-specific stem cells" (containing the patient's DNA/genetic makeup) are created. It involves taking an egg from which the nucleus has been removed, and replacing that nucleus with DNA from the cell of another organism. This results in an early stage embryo with about 100 cells and almost identical DNA to the original organism. This is fundamentally different from, and not to be confused with, human reproductive cloning where a living person would be created.

Therapeutic cloning research has been legal under strict conditions in Australia since 2006. The Research Involving Human Embryos Act 2002 was amended to include therapeutic cloning in 2006. Please see the Embryonic Stem Cell Legislation – Australian Government link above.

What is stem cell therapy?

Stem cell therapy involves the introduction of stem cells into damaged tissues in order to treat a disease or injury. For this form of therapy to be successful, scientists must be able to produce large numbers of stem cells, turn them into the desired specialised cell types, transplant the cells and then get these cells to replace the damaged or destroyed tissues. A number of adult stem cell treatments exist already, particularly bone marrow transplants that are used to treat leukemia. Medical researchers hope to be able to use technologies produced from stem cell research to treat a wider variety of illnesses in the future.

Where are stem cell treatments for spinal cord injury taking place?

There are currently no approved stem cell treatments available. It is important to note that the leap from the laboratory to the clinic is difficult. Many therapies that have been proven to work in animals in the laboratory have failed to work when tested in humans.

There is one early-stage (Phase I, safety) clinical trial currently being undertaken on ES cells. This is the Geron study into the safety of human ES cells transplanted into the spinal cord of acutely injured patients (www.geron.com/media/pressview.aspx?id=863). It is the first human embryonic stem cell-derived therapy to be approved by the Food and Drug Administration (FDA). The trial is a ground-breaking study that will help researchers learn how to use cellular therapies in humans.

Stem cell treatments that have not been approved by regulatory agencies are underway around the world and include India (Dr Geeta Shroff) and China (Dr Hongyun Huang).

Is stem cell therapy in spinal cord injury effective?

The effectiveness of stem cell therapy has yet to be determined. Experimental studies offered in parts of China, India and other countries have not been scientifically proven to be safe or effective.

1. The International Society for Stem Cell Research has compiled a patient handbook and guidelines for the responsible development of safe and effective stem cell therapies. http://www.isscr.org/clinical_trans/index.cfm
2. From July 2009, The Australian Stem Cell Centre will have a "Patient Kit" to help people critically analyse stem cell treatments available overseas. Follow the links from the Australian Stem Cell Centre home page.
3. The Australian Science Media Centre has gathered interviews from some of Australia's top stem cell scientists discussing "stem cell tourism." http://www.aussmc.org/Stem_cell_tourism_briefing.php

Where can I get advice?

- → Always consult with your treating doctor.
- → The Craig Hospital-Denver, Colorado USA – look in "Being an informed consumer" section. http://www.craighospital.org/SCI/educationalTracts.asp
- → The International Campaign for Cures of Spinal Cord Injury Paralysis ("Experimental Treatments for Spinal Cord Injury: what you should know if you are considering participation in a clinical trial") http://www.icord.org/ICCP/Experimental_treatment_for_SCI-full.pdf

This position statement was prepared in collaboration with the Australia and New Zealand Spinal Cord Society. Images kindly supplied by the Australian Stem Cell Centre.

The Australia New Zealand Spinal Cord Injury Network (ANZSCIN) is a bi-national network of leading researchers, clinicians, key stakeholders and people with a spinal cord injury who are committed to a coordinated approach to advancing treatments for spinal cord injury. ANZSCIN is supported by the Office of Science and Medical Research. For more information visit **www.anzscin.org**

The Australia and New Zealand Spinal Cord Society (ANZSCoS) is an impartial, non-political and non-profit making association whose objective is to promote high quality management of people with spinal cord lesions throughout Australia and New Zealand. It aims to study any and all problems relating to people with traumatic and non-traumatic lesions of the spinal cord including; causes, prevention, basic and clinical research, medical and surgical management, clinical practice, education, rehabilitation and social reintegration.

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