

MEDIA RELEASE

ON THE CUSP OF A TREATMENT - CLINICAL TRIAL ON TRACK FOR 2020

A global spinal injury research project taking place on the Gold Coast is inching closer to its goal of a treatment for paralysis with an independent contract research organisation (CRO) appointed this week to progress a potential human clinical trial in 2020.

The major research therapy is currently Australia's greatest hope of a treatment for chronic spinal cord injuries and is known as the Spinal Injury Project (SIP).

SIP involves taking a special type of cell from a patient's olfactory (sense of smell) system and transplanting it into the spinal cord injury site - while creating a 3D bio-degradable nerve cell bridge that can be transplanted to repair injured spinal cords.

The ground-breaking project is being progressed by a team of international scientists at Griffith University at the Gold Coast and Brisbane and carries on the findings originally pioneered by 2017 Australian of the Year Professor Emeritus Alan Mackay-Sim.

The appointment of an independent CRO is a major milestone for the project, as it further propels the possibility of a human clinical trial commencing next year.

SIP Team Leader Associate Professor James St John says it's an exciting time for the Spinal Injury Project with research also on track and results better than expected.

"The past few months has proved particularly exciting with some of our research outcomes proving better than expected and timelines for delivery meeting predicted expectations," he said.

"Our latest major break-through has involved getting the 3D nerve bridges to integrate successfully into the injured spinal cord which then helps the nerve cells to grow across the injury site "

"The appointment of Neuroscience Trials Australia as a CRO will allow us to identify appropriate project partners, the design and size of the clinical trial and also predict final cost estimates of immediate and future phases.

"Pending the outcomes and future funding, we are on track for the trial to commence at the end of 2020."

The independent assessment of the SIP human clinical trial will be conducted over a three month period. Following the results the SIP team, in conjunction with its major funding partners including the Perry Cross Spinal Research Foundation (PCSRF), will 'do everything it possibly can' to keep the wheels in motion of the trial.

Founder of the Perry Cross Spinal Research Foundation, Perry Cross, says the planned human clinical trial can't come quick enough for the 15,000 Australians currently living with and affected by paralysis.

"We're thrilled to see a CRO appointed to this major Australian trial and get our next steps and plan in place following it, so the goal posts we've set for late 2020 aren't set back," he said.

"The 'know-how' is there, we just need to keep up the funding so this exceptional team of scientists can continue to progress the therapy."

A/Prof St John says while the major project is heading in the right direction and has shown proof-in-principal results in restoring function of movement, there was still a long road ahead to ensure the therapy wasn't rushed and had the best possible outcomes.

"Due to the major funding required for a project of this scale, we are working towards only having 'one shot' at it. We have to get it right," he said.

"Therefore, it's not something we want to rush, even if the excitement is there. In addition to the independent assessment of the trial and our continued research progression, the other major component of SIP is the rehabilitation side.

"To ensure the therapy has the best chance of success, an intense rehabilitation program must follow the cell therapy. "

The Perry Cross Spinal Research Foundation is currently working towards providing funding for the rehabilitation program.

"The rehabilitation trial - known as the Sustained Functional Therapy trial can commence as soon as funding is in place. It costs \$1.6M and we're urgently seeking support to provide this."

For Background:

The **Spinal Injury Research** Project was pioneered by 2017 Australian of the Year Professor Emeritus Alan Mackay-Sim and other scientists from around the world.

A world first Phase I clinical trial led by Prof Mackay-Sim at Griffith University, in 2002 demonstrated that the therapy is safe for use in humans. That trial led to a recent human trial by British/Polish researchers that demonstrated that restoration of function after severing of the human spinal cord is indeed possible. In this study, a mix of olfactory ensheathing cells and fibroblasts together with a nerve bridge were transplanted into the injured spinal cord. Within 6-12 months after transplantation, the patient, who had been paralysed for several years prior to the treatment, regained some motor function of his legs, bladder control, and sensation.

These exciting proof-of-principle results give hope that patients may regain function after spinal cord injury. What is now needed is to improve the transplantation therapy to make it more effective.

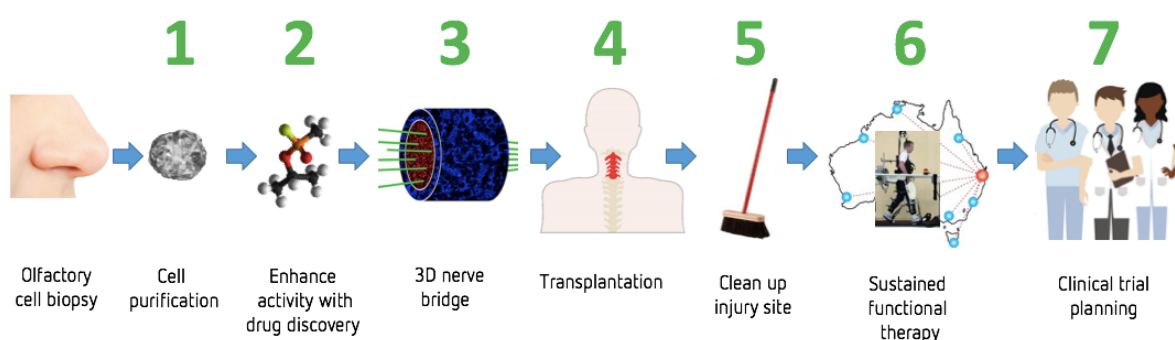
In partnership with the Perry Cross Spinal Research Foundation, the team at Griffith University is planning to undertake a clinical trial to progress this journey and show that this therapy can further regenerate patients' sensory and motor function.

Clinical Trial:

The clinical trial will involve taking olfactory cells from the own patient's nose, the cells will be purified, enhanced and implanted into the patient's spinal cord, followed by intensive rehabilitation to promote nerve regeneration.

As part of the Spinal Injury Project, there are seven essential components needed for an effective therapy:

Seven components for an effective therapy



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