Griffith UNIVERSITY
Queensland, Australia

Spinal injury project

Olfactory cell nerve bridge and high-frequency, long-term rehabilitation clinical trial

How does the therapy work?

This therapy uses a patient's own special regenerative cells from inside their nose. Cells are obtained via a simple nasal biopsy and made into therapeutic nerve bridges which will be placed into the injury site via a surgical operation. To enable the best outcomes for the treatment, participants will undergo priming rehabilitation before receiving the nerve bridges, and regenerative rehabilitation afterwards. For more details, see the virtual lab tour of the Clem Jones Centre labs.

When will the EOI date be announced?

We are working with the hospital to get final approval for the trial. We will let the community know when the EOI page is active and ready to take applications.

Where do I apply for the clinical trial?

Participant recruitment will begin soon. To receive a notification when EOIs open, please enter your email on the EOI registration page linked here: EOI registration

How do I get more information about the clinical trial?

For more details about our trial, please visit; Spinal cord injury nerve bridge transplantation trial (griffith.edu.au), or to see more of what we do at the lab visit our linktree.

How do I stay up to date on clinical trial developments?

Follow our social media platforms here. We will announce the start of participant recruitment and share all relevant trial information on social media, and share progress of the trial once it commences. We will release interim results where possible.

What are the inclusion and exclusion criteria for the clinical trial?

Participants will have an acquired spinal cord injury. Initially, recruitment will be limited to individuals with complete injuries (AIS A or B) that are over 12 months old, from C5 to low thoracic, but not lumbar. Once safety is established within this group, recruitment will move to include AIS C injuries at least 4 months old.

Full inclusion and exclusion criteria and more about the trial please visit the links below.

Spinal cord injury nerve bridge transplantation trial (griffith.edu.au)

Clinical Trial ANZCTR

Please note that the inclusion/exclusion criteria are being updated in the next protocol amendment to remove any COVID vaccination requirements.

How old do you have to be, to be part of the Clinical Trial?

Participants must be at least 18 years old to be part of the trial.

Is there a maximum age limit?

While there is a minimum age limit (18+), there is no maximum age limit. We encourage anyone above the minimum age to apply, however the requirement to undertake exercise rehabilitation for three hours a day, five days a week for 11 months should be considered.

I have a high level SCI above C5 level, am I eligible to be a part of the trial?

Clinicans have advised us that high level (C1-C4) spinal cord injuries will be excluded from the clinical trial due to risks involving respiration. This does not mean that higher level injuries won't be included in future trials. In fact, please still register your interest/apply as this is valuable evidence to show the interest of people with high-level injuries in being part of a cell and rehabilitation clinical trial.

I have an incomplete injury, am I eligible for the trial?
Yes, people with incomplete injuries (AIS C) are eligible, but will not be recruited until later in the trial. Initially, the trial will recruit individuals with a complete spinal cord injury (AIS A and B) to first establish safety. We will then recruit people who have incomplete SCI.

I have a peripheral nerve injury, am I eligible for the clinical trial?

This trial is only for people with SCI. However, we are working on a therapy to treat peripheral nerve injuries. We encourage you to join our Peripheral Nerve Injury (PNI)

Consumer Panel. This panel brings together individuals with firsthand experience of peripheral nerve injuries to share insights on the challenges they face. Our goal is to incorporate these perspectives into our research to improve outcomes.

We are engaging around 5-6 people, and the panel meets every three months. Participants receive $100 per one-hour session to recognise their time and input. These meetings provide a forum to discuss experiences with PNI, and panel members have many opportunities to contribute to our upcoming grants as collaborators.

If you're interested, please email Dr Jasmine Kaur (jasmine.kaur@griffith.edu.au).

I don't live in Queensland, can I sign up?
The trial will recruit people who live, or will live, in South East Queensland, northern NSW, Sydney or Melbourne and can travel each day to the rehabilitation providers, Making Strides (Gold Coast), Royal Rehab (Sydney) or The Next Step (Melbourne). At the start of the trial, we will recruit people who live in SE Qld or northern NSW to test feasibility of delivering the program of cell transplantation and rehabilitation. People from Sydney and Melbourne will be recruited once this feasibility is established.

How do I meet the team and tour the facilities?
If you are ever in the Gold Coast and would like to tour our facilities, you can do so by signing up here.

I need more support.

If you feel like you need some more support in navigating your injury or the decision to take part in this trial, we recommend joining the Perry Cross Spinal Research Foundation mailing list. This community provides access to valuable resources and support for those affected by spinal cord injuries. They also coordinate lab tours at our Gold Coast campus where you can learn more about our ongoing research firsthand.
For more information, visit: pcsrf.org.au/ or contact team@pcsrf.org.au.

What type of visa do I need to be on if I am not an Australian citizen

You need to be on a valid visa with an end date beyond the end of the trial. You cannot be on a tourist visa.

Is it possible to personally pay for an additional, guaranteed place in the trial?

No, participants will not be able to pay to guarantee a place in the trial.

Will I be able to express interest in enrolling in the trial control group only?

Due to clinical trial regulations, participants cannot choose which group they will be in. The group allocation will be randomly selected.

What if I am selected in the control group, but I wish to receive the cell therapy? Will I be able to receive the cell therapy regardless?

If you are assigned to be in the control group, you will not receive the cell transplantation therapy. The research team is planning for the next trial and is considering how people in the control group of this first trial could be included in the treatment group of the next trial.

I have metalwork around my injury. Will that affect my eligibility?

To improve medical imaging it would be best to have metalwork implants removed from around the injury site. The trial clinicians will assess the metalwork at the start of the trial and if it is safe to do so participants will undergo an operation to remove the metalwork. This operation will be done before starting the three months of prehabilitation therapy.

I have had nerve and/or tendon surgery in my upper limb. Does that affect my eligibility?

We understand that many people have had various types of interventions. In general, these do not affect eligibility, however the clinical team will assess you to ensure there are no potential complications or contraindications.

I have had stem cell treatment for my injury. Does that affect my eligibility?

We understand that many people have had various types of interventions. In general, a stem cell treatment will not affect eligibility, unless it has been done recently. The clinical team will assess you to ensure there are no potential complications or contraindications.

Will it cost me anything to be part of the trial?

All costs for surgeries, hospital appointments, assessments and rehabilitation are covered by the trial. The costs of interstate transport and accommodation for Melbourne and Sydney participants will be covered by the trial. Participants will be reimbursed for local travel costs and for the time they spend undertaking trial activities.

Is someone who is unable to have an MRI excluded from the study?

Being able to have an MRI is required for the study. Please discuss your personal circumstance with the clinical team to determine whether MRI can be provided for you.