Phase 2 Randomised controlled trial of bone-marrow derived mesenchymal stromal cells (MSC) for new onset chronic lung allograft dysfunction (CLAD)

ACTRN12616000338460

Status	RECRUITING
Phase	Phase 2
Sponsor	University of Queensland
Enrollment	82 participants

Plain Language Summary

This study tests whether infusions of special stem cells called mesenchymal stromal cells (MSC) can slow or stop a serious lung condition called chronic lung allograft dysfunction (CLAD) in people who have had a lung transplant. CLAD causes the transplanted lungs to gradually stop working, and there is currently no reliable treatment. Participants receive four infusions over two weeks and are followed for a year to monitor lung function.

You may be eligible if:
- You are 18 years of age or older and have had a bilateral (two-lung) transplant at least 6 months ago
- You have recently developed CLAD (a persistent drop in lung function of 20% or more in the past 12 months)
- Other causes of lung function decline (like infection or rejection) have been ruled out
- Your immunosuppression medications have been stable for 4 weeks
- You are available for all required study visits and procedures, including bronchoscopies

You may NOT be eligible if:
- You have an untreated rejection or active infection
- You have received certain treatments (macrolide antibiotics, IV steroids, photopheresis, or radiation) in the past 4 weeks
- You are pregnant or breastfeeding
- You are allergic to beef products
- You are enrolled in another interventional clinical trial

Talk to your doctor about whether this trial might be right for you.

Key Eligibility Criteria

Inclusion (5)

- Bilateral lung transplant recipients aged greater or equal to 18 years and at least 6 months post-transplant. Patients with other organs transplanted (eg heart, liver, kidney) or those who have undergone lobar transplantation, or re-transplantation, are potentially eligible.
- New-onset CLAD (defined as a persistent (3weeks apart) fall in FEV1 of at least 20% from the mean of the two best post-transplant values taken at least 3 weeks apart) in the 12 months prior to the screening visit. Other causes of a fall in FEV1 (acute cellular or humoral rejection, active infection, anastomotic stenosis etc.) must be excluded as per international guidelines.
- Stable immunosuppression regimen, as assessed by the investigator, in the 4 weeks prior to the screening visit.
- Available for all specified assessments at the study site through the completion of the study, including the protocol bronchoscopies.
- Provision of written informed consent.

Exclusion (11)

https://www.anzctr.org.au/Trial/Registration/TrialReview.aspx?ACTRN=ACTRN12616000338460

• Any condition that in the opinion of the Investigator may interfere with the safety of the patient, his / her completion of required follow-up visits or evaluation of the study objectives

• Untreated cellular or humoral rejection

• Clinically meaningful and untreated viral, bacterial or fungal infection

• Use of azithromycin or another macrolide antibiotic, if commenced within 4 weeks of the screening visit

• Intravenous pulsed methylprednisolone, within 4 weeks of the screening visit

... and 6 more (see full listing online)

Locations (5 total)

The Prince Charles Hospital - Chermside, NSW,QLD,SA,WA,VIC, Australia
St Vincent's Hospital (Darlinghurst) - Darlinghurst, NSW,QLD,SA,WA,VIC, Australia
Fiona Stanley Hospital - Murdoch, NSW,QLD,SA,WA,VIC, Australia
... and 2 more locations