

Phase I trial of multi-virus-specific T cells for paediatric haploidentical -stem cell transplant recipients

ACTRN12620000141943

Status	RECRUITING
Phase	Phase 1
Sponsor	QIMR Berghofer Medical Research Institute
Enrollment	20 participants

Plain Language Summary

Children who receive a stem cell transplant from a partially matched (haploidentical) donor are at high risk of serious viral infections because the transplant process requires removing immune cells — including the T cells that normally fight viruses — before the transplant is given. This leaves children vulnerable, sometimes fatally so, in the weeks and months after transplant.

This Phase 1 trial tests a new preventative therapy: virus-fighting T cells grown in the laboratory from the transplant donor's blood, then given to the child after transplant. The therapy targets four common viruses that frequently cause serious illness in these children. The primary goal is to confirm that this approach is safe and that the donated T cells can help rebuild the child's immune defences.

You may be eligible if your child is aged 3 months to 18 years, requires a haploidentical stem cell transplant, and has a willing and eligible donor aged 18 or over who can provide blood for the therapy. Participation in the treatment phase requires additional criteria to be met at the time of the planned infusions.

Key Eligibility Criteria

Inclusion (6)

- Aged between 3 months and 18 years
- Patient has a condition for which HSCT is indicated
- Transplant physician determines that optimal donor is haploidentical*
- Haplo-HSCT donor is aged 18 or above
- Haplo-HSCT donor is available and willing to donate blood for therapy manufacture
- ... and 1 more (see full listing online)

Exclusion (2)

- The treatment protocol in part or in its entirety is declined by either the patient or their legal guardian.
- NB: Additional criteria are in place for the commencement of infusions

Locations (1 total)

NSW,QLD,VIC, Australia

<https://www.anzctr.org.au/Trial/Registration/TrialReview.aspx?ACTRN=ACTRN12620000141943>

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