

A phase II study of haploidentical peripheral blood stem cell transplantation with post-transplant cyclophosphamide as Graft versus Host Disease (GVHD) prophylaxis

ACTRN12617000151336

Status	RECRUITING
Phase	Phase 2
Sponsor	St Vincent's Hospital Sydney
Enrollment	70 participants

Plain Language Summary

This study is for people with blood cancers (such as leukaemia or lymphoma) who need a stem cell transplant but do not have a perfectly matched donor. It uses a transplant from a half-matched family member (called a haploidentical transplant) and then uses a medication called cyclophosphamide shortly after the transplant to prevent the body from attacking the new cells (a complication called Graft versus Host Disease, or GVHD).

You may be eligible if:

- You are between 16 and 70 years old
- You have a blood cancer (such as AML, MDS, ALL, CML, or lymphoma) that needs a transplant
- You do not have a fully matched related or unrelated donor
- You have a close family member who is a half-match (haploidentical)
- Your heart, lungs, and kidneys are functioning adequately

You may NOT be eligible if:

- You are pregnant
- You are HIV positive
- Cancer has spread to the brain and is not responding to treatment
- You have serious organ failure
- Your life expectancy is less than 60 days
- You cannot provide written consent

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

Key Eligibility Criteria

Inclusion (16)

- Patients 16 – 70 years of age
- Recipients must have a haematological malignancy with a significant risk of relapse (as measured by the Disease Risk Index), where allogeneic transplant is indicated.
- Adults without a readily available matched related or unrelated donor.
- Patients must have a first-degree relative who are 3/6 to 4/6 HLA matched.
- Patients with an HCT-CI/age > or equal to 3 will receive non-myeloablative conditioning.
- ... and 11 more (see full listing online)

Exclusion (6)

- Pregnancy.
- Positive serology for HIV.

<https://refractory-central.net/Res/Study/ACTRN=ACTRN12617000151336>

- Serious organ dysfunction: LVEF <50%, FEV1, FVC, DLCO <50%of predicted, LFT > 5 x the upper limit of normal, or creatinine clearance < 40 ml/min .
 - Life expectancy less than 60 days.
- ... and 1 more (see full listing online)

Locations (6 total)

Westmead Hospital - Westmead, NSW,VIC, Australia
St Vincent's Hospital (Darlinghurst) - Darlinghurst, NSW,VIC, Australia
Royal North Shore Hospital - St Leonards, NSW,VIC, Australia
... and 3 more locations