

Safety Study of Unlicensed IND Cord Blood Units Manufactured by the National Cord Blood Program for Unrelated Transplantation

Status: RECRUITING

Eligibility Criteria

Sex: ALL

Age:

Healthy Volunteers: This study is NOT accepting healthy volunteers

Inclusion Criteria:

1. Diagnosis: Patients with disorders affecting the hematopoietic system that are inherited, acquired, or result from myeloablative treatment.
2. Patients: Patients of any age and either gender
3. Cord blood product manufactured by the NCBP (at least one, if the graft contains more than one units)

Exclusion Criteria:

1. Patients who are receiving licensed cord blood products (only)
2. Patients who are receiving unlicensed cord blood products from other banks (only)
3. Patients who are transplanted at non-US transplant centers
4. Patients who are receiving cord blood products that will be "manipulated" post-thaw (e.g., ex vivo expansion, incubation in vitro, etc.)

Conditions & Interventions

Interventions:

BIOLOGICAL: unlicensed CBU

Conditions:

Infusion Reactions

Keywords:

cord blood, transplantation, stem cells, adverse event

More Information

Description:

This study will evaluate the safety of infusion of the investigational cord blood units by carefully documenting all infusion-related problems.

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Principal Investigator ID:

Phase: PHASE2

IRB Number:

System ID: NCT01656603

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