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# P3 Study of Umbilical Cord Blood Cells Expanded With MPCs for Transplantation in Patients With Hematologic Malignancies

**This study is currently recruiting participants.**

*Verified August 2013 by Mesoblast, Ltd.*

**Sponsor:**
Mesoblast, Ltd.

**Information provided by (Responsible Party):**
Mesoblast, Ltd.

**ClinicalTrials.gov Identifier:**
NCT01854567

First received: May 13, 2013
Last updated: August 22, 2013
Last verified: August 2013
History of Changes

Full Text View | Tabular View | No Study Results Posted | Disclaimer | How to Read a Study Record

## Purpose

The study investigates the time to engraftment of a mesenchymal expanded **cord blood** unit in patients with hematologic malignancies undergoing transplantation with myeloablative conditioning.

| Condition | Intervention | Phase |
|---|---|---|
| Acute Myelogenous Leukemia<br>Acute Lymphoblastic Leukemia<br>Non-Hodgkin's Lymphoma<br>**Hodgkin's Disease** | Biological: Infusion of one MPC expanded **cord** unit and one unexpanded **cord** unit<br>Biological: Infusion of two unexpanded **cord blood** units. | Phase 3 |

Study Type: Interventional
Study Design: Allocation: Randomized
Endpoint Classification: Safety/Efficacy Study
Intervention Model: Parallel Assignment
Masking: Open Label
Primary Purpose: Treatment

Official Title: A 1-Year, Multicenter, Randomized, Open-Label Controlled Study to Evaluate the Efficacy and Safety of **Cord Blood** Cells Expanded With MPCs for Hematopoetic Recovery in Patients With Hematologic Malignancies After Myeloablative Treatment

**Resource links provided by NLM:**

Genetics Home Reference related topics: familial acute myeloid leukemia with mutated CEBPA

MedlinePlus related topics: Acute Myeloid Leukemia Cancer Chronic Lymphocytic Leukemia Hodgkin Disease Leukemia Lymphoma

U.S. FDA Resources

**Further study details as provided by Mesoblast, Ltd.:**

Primary Outcome Measures:

- Time to Neutrophil and Platelet Engraftment [ Time Frame: 100 days ] [ Designated as safety issue: No ]

Secondary Outcome Measures:

- Proportion of subjects with neutrophil recovery at day 26, platelet recovery at day 60 and subjects alive at day 100 [ Time Frame: 100 days ] [ Designated as safety issue: No ]

- Percentage of patients with primary graft failure [ Time Frame: 100 days ] [ Designated as safety issue: Yes ]

Other Outcome Measures:

- Incidence and severity of acute Graft Versus Host Disease [ Time Frame: 100 days ] [ Designated as safety issue: Yes ]

Estimated Enrollment: 240
Study Start Date: February 2013
Estimated Study Completion Date: July 2018
Estimated Primary Completion Date: February 2018 (Final data collection date for primary outcome measure)

| Arms | Assigned Interventions |
|---|---|
| Experimental: Active<br>Infusion of one MPC expanded **cord** unit and one unexpanded **cord** unit. | Biological: Infusion of one MPC expanded **cord** unit and one unexpanded **cord** unit<br>Infusion of one MPC expanded **cord** unit and one unexpanded **cord** unit. |
| Active Comparator: Control<br>Infusion of two unexpanded **cord blood** units. | Biological: Infusion of two unexpanded **cord blood** units.<br>**Umbilical Cord Blood**. |

## Eligibility

Ages Eligible for Study: up to 65 Years
Genders Eligible for Study: Both
Accepts Healthy Volunteers: No

**Criteria**
Inclusion Criteria:

- Patient must have one of the following:
  - Acute myelogenous leukemia (AML) in complete morphological remission at study screening (Complete Remission with Incomplete Platelet Recovery (CRp) acceptable).
  - Acute lymphoblastic leukemia (ALL) in complete morphological remission at study screening (Complete Remission with Incomplete Platelet Recovery (CRp) acceptable).
  - Non-Hodgkin's lymphoma (NHL): High risk subjects with responsive disease after first relapse. High risk includes those with Burkitt's Lymphoma and those with extensive marrow involvement at diagnosis-precluding autologous transplant.
  - Hodgkin's disease: High risk subjects with responsive disease after first relapse.
- Minimum Karnofsky Scale
- Subject must weigh at least 20 kg
- Up to 65 years of age
- Adequate major organ system function

Exclusion Criteria:

- Pregnancy and/or lactating
- Suitable, 6/6 HLA matched related sibling donor available
- Previous participation in a stem cell study within last 30 days

## Contacts and Locations

Please refer to this study by its ClinicalTrials.gov identifier: NCT01854567

**Contacts**

Contact: Rebecca Cohen rebecca.cohen@mesoblast.com

**Locations**

**United States, Florida**

Moffitt Cancer Center **Recruiting**
Tampa, Florida, United States, 33612

Principal Investigator: Marcie Tomblyn, MD

**United States, New York**

Weill Cornell-New York Presbyterian Hospital — **Recruiting**
New York, New York, United States, 10065
Principal Investigator: Tsiporah B Shore, MD

Westchester Medical Center — **Recruiting**
Valhalla, New York, United States, 10595
Principal Investigator: Mitchell Cairo, MD

**United States, Ohio**

Case Western — **Recruiting**
Cleveland, Ohio, United States, 44106
Principal Investigator: Hillard Lazarus, MD
Sub-Investigator: Marcos deLima, MD

**United States, Texas**

MD Anderson Cancer Center — **Recruiting**
Houston, Texas, United States, 77030
Principal Investigator: Elizabeth J Shpall, MD

Texas Transplant Center at Methodist Healthcare System — **Recruiting**
San Antonio, Texas, United States, 78229
Principal Investigator: Paul Shaughnessy, MD

**Sponsors and Collaborators**

Mesoblast, Ltd.

**Investigators**

| | | |
|---|---|---|
| Study Director: | Donna Skerrett, MD, MS | Mesoblast, Ltd. |
| Principal Investigator: | Elizabeth J. Shpall, MD | M.D. Anderson Cancer Center |

## More Information

No publications provided

| | |
|---|---|
| Responsible Party: | Mesoblast, Ltd. |
| ClinicalTrials.gov Identifier: | NCT01854567 History of Changes |
| Other Study ID Numbers: | CB-AB006, 2012-0166 |
| Study First Received: | May 13, 2013 |
| Last Updated: | August 22, 2013 |
| Health Authority: | United States: Food and Drug Administration |

Keywords provided by Mesoblast, Ltd.:

| | |
|---|---|
| **Cord Blood** | AML |
| Stem Cells | ALL |
| MPC | NHL |
| Mesoblast | Leukemia |
| Expanded | Lymphoma |

Additional relevant MeSH terms:

| | |
|---|---|
| **Hodgkin Disease** | Leukemia, Myeloid, Acute |
| Lymphoproliferative **Disorders** | Leukemia, Myeloid |
| Lymphatic **Diseases** | Lymphoma |
| Immunoproliferative **Disorders** | Lymphoma, Non-Hodgkin |
| Immune System **Diseases** | Hematologic Neoplasms |
| Hematologic **Diseases** | Neoplasms by Histologic Type |
| Leukemia | Neoplasms |
| Leukemia, Lymphoid | Neoplasms by Site |
| Precursor Cell Lymphoblastic Leukemia-Lymphoma | |

ClinicalTrials.gov processed this record on September 22, 2013