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Trial record **1 of 101** for: Acute Myeloid Leukaemia and cord blood
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Reduction of Cord Blood Transplantation Toxicity in Patients With Acute Myeloid Leukemia (MINICORD)

This study has been completed.

Sponsor:
Assistance Publique - Hôpitaux de Paris

Information provided by (Responsible Party):
Assistance Publique - Hôpitaux de Paris

ClinicalTrials.gov Identifier:
NCT00797758

First received: November 24, 2008
Last updated: March 7, 2013
Last verified: March 2013
History of Changes

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

Purpose

Multicentric evaluation of the reduction of unrelated **cord blood** transplantation (UCBT) toxicity by using reduced intensity conditioning (RIC) in patients with **acute myeloid leukaemia**.UCBT related mortality and morbidity were limiting factors for the development of this procedure in adults. Non myeloablative conditioning regimen showed promising results and prospective evaluation has to be developed to confirm these retrospective data.

Condition	Intervention	Phase
Acute Myeloid Leukemia	Other: **Cord blood** transplantation	Phase 2

Study Type: Interventional
Study Design: Allocation: Non-Randomized
Endpoint Classification: Safety Study
Intervention Model: Single Group Assignment
Masking: Open Label
Primary Purpose: Treatment

Official Title: Assessment of Reduction of **Cord Blood** Transplantation Toxicity by Using Reduced Intensity Conditioning in Patients With **Acute Myeloid Leukemia**.

Resource links provided by NLM:

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

MedlinePlus related topics: Acute Myeloid Leukemia Leukemia

U.S. FDA Resources

Further study details as provided by Assistance Publique - Hôpitaux de Paris:

Primary Outcome Measures:

- Transplant related mortality [Time Frame: At 2 years] [Designated as safety issue: Yes]

Secondary Outcome Measures:

- Clinical efficiency (overall survival, event free survival, relapse incidence, **acute** and chronic GVHD incidence, graft failure, venoocclusive disease, interstitial pneumonia, infections, comorbidity score, quality of life and medico-economic impact) [Time Frame: at 2 years] [Designated as safety issue: No]

Enrollment: 76

Study Start Date: October 2007
Study Completion Date: December 2011
Primary Completion Date: July 2011 (Final data collection date for primary outcome measure)

Arms	Assigned Interventions
Experimental: 1 Umbilical **cord blood** transplantation after reduced intensity conditioning	Other: **Cord blood** transplantation Umbilical **cord blood** transplantation after reduced intensity conditioning Other Name: **Cord blood** transplantation

Detailed Description:

Individual meta-analysis is planned to compare geno-identical transplantation with myeloid-ablative or non myeloid-ablative conditioning with UCBT after RIC.

Eligibility

Ages Eligible for Study: 4 Years to 65 Years
Genders Eligible for Study: Both
Accepts Healthy Volunteers: No

Criteria

Inclusion Criteria:

- Ages : 4 to 65
- De novo or secondary AML requiring allogeneic transplant
- No donor (related or unrelated) compatible 10/10
- Complete remission excepted CR1 with t(8;21) or inv (16) or t (15;17)
- Smouldering AML without progression
- Signed assent of recipient

Exclusion Criteria:

- If CR1: AML with with t(8;21) or inv (16) or t (15;17)
- Karnofsky < 50% - Clearance of creatinin < 40 ml/min
- Transaminases > 8 N
- Previous autologous or allogeneic transplantation within 6 month prior to the study (except if tandem)
- total body irradiation contra-indicating 2 Gy TBI
- local irradiation contra-indicating 2 Gy TBI

Contacts and Locations

Please refer to this study by its ClinicalTrials.gov identifier: NCT00797758

Locations

France

Département d'Hématologie et d'Oncologie Médicale, Hôtel-Dieu
Paris, France, 75001

Sponsors and Collaborators

Assistance Publique - Hôpitaux de Paris

Investigators

Principal Investigator: Bernard RIO, MD, PhD Assistance Publique - Hôpitaux de Paris

More Information

No publications provided

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Other Study ID Numbers: P 060206
Study First Received: November 24, 2008
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Health Authority: France: Ministry of Health

Keywords provided by Assistance Publique - Hôpitaux de Paris:

Cord blood transplantation
Conditioning regimen
Acute myeloid leukaemia
SORROR comorbidity index
Quality of life
Innate immunity
Immune reconstitution post transplant
Umbilical **Cord Blood** Stem Cell Transplantation
Hematopoietic Stem Cell Transplantation

Additional relevant MeSH terms:

Leukemia
Leukemia, Myeloid, **Acute**
Leukemia, Myeloid
Neoplasms by Histologic Type
Neoplasms

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