

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Haploidentical Hematopoietic Stem Cell Transplantation in the Treatment of Hematological Malignancies Using CAMPATH-1H

Protocol summary

Summary

In this study, we are going to study the feasibility of transplantation from semi-matched (haploidentical) related donors in patients. We transplant 10 patients who haven't any HLA matched related or unrelated donors with haploidentical related donor and CAMPATH and survey them with WBC and Platelet recovery and one six months survival.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138706061030N2**

Registration date: **2008-09-29, 1387/07/08**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2008-09-29, 1387/07/08

Registrant information

Name

Mahdi Jalili

Name of organization / entity

Hematology-Oncology & SCT Research Center

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Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Sciences

Expected recruitment start date

2006-09-01, 1385/06/10

Expected recruitment end date

2008-02-01, 1386/11/12

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Haploidentical Hematopoietic Stem Cell Transplantation in the Treatment of Hematological Malignancies Using CAMPATH-1H

Public title

Feasibility of Haploidentical Hematopoietic Stem Cell Transplantation Using CAMPATH-1H

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion Criteria: Recipient: Ages 5-50 years Acute myelogenous leukemia (AML) or acute lymphoblastic leukemia (ALL) Second remission (CR2) in standard risk patients or CR1 in cases with high-risk features (poor cytogenetic changes or secondary to myelodysplastic syndrome) Unavailability of HLA identical related donor or matched unrelated donor. Unavailability of other therapeutic intervention that prolongs patient survival. No history of allergy to CAMPATH. Donor: The donor must be haploidentical with the recipient. Weight greater than or equal to 18 kg. Age between 2 and 60 years old. Negative two-way WBC crossmatch with the recipient. Exclusion Criteria: Major anticipated illness or organ failure incompatible with survival from transplantation. Severe psychiatric illness. Mental deficiency sufficiently severe as to make compliance with the transplantation procedure unlikely and making informed consent impossible. HIV positive Active infection Recipient: Positive pregnancy test for women of childbearing age. Left ventricular ejection fraction less than 40% AST/SGOT

greater than 20 x ULN (CTCAE grade IV v3.0) Bilirubin
greater than 10 x ULN (CTCAE grade IV v3.0) Creatinine
greater than 6 x ULN (CTCAE grade IV v 3.0) Donor:
Pregnant or lactating Unfit to receive filgrastim (G-CSF)
and undergo apheresis (abnormal blood counts, history
of stroke, uncontrolled hypertension) Sickling
hemoglobinopathies including HbSS, HbAS, HbSC HbAg
positive CMV positive (for CMV negative recipients)

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **10**

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Single

Other design features

Secondary Ids

1

Registry name

clinicaltrials.gov

Secondary trial Id

NCT00458250

Registration date

2007-08-01, 1386/05/10

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of HORC-BMT

Street address

Kargar Ave. Shariati Hospital

City

Tehran

Postal code

14114

Approval date

2006-10-28, 1385/08/06

Ethics committee reference number

2255/418/الف

Health conditions studied

1

Description of health condition studied

Haploidentical Hematopoietic Stem Cell Transplantation

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Engraftment one month after transplantation

Timepoint

30 days from transplantation

Method of measurement

Count of WBC and Platelet

Secondary outcomes

1

Description

six months survival

Timepoint

180 days after transplantation

Method of measurement

Live patients after 180 days

Intervention groups

1

Description

Procedure: Haploidentical hematopoietic stem cell
transplantation Drug:

Busulfan,Cyclophosphamide,CAMPATH-1H,Cyclosporin
A,Methotrexate

Category

empty

Recruitment centers

1

Recruitment center

Name of recruitment center

Hematology-Oncology and SCT Research Center

Full name of responsible person

Mohammadreza Ostadali

Street address

Kargar Ave. Shariati Hospital

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Tehran University of Medical Sciences

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Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Tehran University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

empty

Person responsible for general inquiries

Contact**Name of organization / entity**

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty