Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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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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 HBsAg 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

City
Tehran

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Tehran University of Medical Sciences
Street address
Tehran University of Medical Sciences
City
Tehran
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

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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