Clinical Trial Protocol
Iranian Registry of Clinical Trials

30 May 2026

Comparison of post-transplantation high dose cyclophosphamide versus Donor lymphocyte infusion (DLI) as relapse prophylaxis after haploidentical stem cell transplantation in high risk acute leukemia: A prospective randomized study

Protocol summary

Summary
In this prospective randomized study totally 18 patients aged between 17-50 years, suffered from acute leukemia and candidate for haploidentical stem cell transplantation, are randomized into 2 arms. First arm receive cyclophosphamide 50 mg/kg at day +3 and other arm receive donor lymphocyte infusion (DLI) from donor after subcutaneous granulocyte colony-stimulating factor (G-CSF) at day +30 with average cell dose 4×10^8 mononuclear cells (MNC)/kg (2.5-6×10^8 MNC/kg). Two groups will be compared for rate of relapse, survival and side effect after one year follow up.

General information

Acronym

IRCT registration information
IRCT registration number: **IRCT201208041030N11**
Registration date: **2012-08-26, 1391/06/05**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date
2012-08-26, 1391/06/05

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
Hematology-Oncology and Stem cell Transplantation Research Center

Expected recruitment start date
2009-11-22, 1388/09/01
Expected recruitment end date
2013-11-22, 1392/09/01
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison of post-transplantation high dose cyclophosphamide versus Donor lymphocyte infusion (DLI) as relapse prophylaxis after haploidentical stem cell transplantation in high risk acute leukemia: A prospective randomized study

Public title
Prophylaxis of relapse with high dose cyclophosphamide or donor lymphocyte infusion (DLI) after haploidentical stem cell transplantation in high risk acute leukemia
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria: Diagnosis of ALL or AML; Status of first complete remission (CR1) in high risk patients and second complete remission (CR2) for others; Age: 17-50; Karnofsky score 70-100; Life expectancy: 12 months; No Full matched donor (Related, Unrelated and Cord Blood);

No candidate for autologous transplantation; Live enzyme < 2 upper normal limit (UNL) and Billirubin < 1.5 UNL; Cr < 1.4; Eject fraction (EF) > 45% and Diffusing Capacity of the Lung for Carbon Monoxide (DLCO) greater than 45%; Human Immunodeficiency Virus (HIV) negative; No addiction. Exclusion criteria: Pregnancy; Breast feeding.

Age
From **17 years** old to **50 years** old

Gender
Both

Phase
2-3

Groups that have been masked
No information

Sample size
Target sample size: **18**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Hematology-Oncology and Stem cell Transplantation Research Center

Street address
Shariati Hospital, Kargar Ave

City
Tehran

Postal code

Approval date
2009-10-08, 1388/07/16

Ethics committee reference number
1388/7/16

Health conditions studied

1

Description of health condition studied
Acute myelblastic leukaemia

ICD-10 code
C92.0

ICD-10 code description
Acute myelblastic leukaemia

2

Description of health condition studied
Acute lymphoblastic leukaemia [ALL]

ICD-10 code
C91.0

ICD-10 code description
Acute lymphoblastic leukaemia [ALL]

Primary outcomes

1

Description
Relapse rate after transplantation

Timepoint
One year after transplantation

Method of measurement
Bone marrow examination

Secondary outcomes

1

Description
One year overall survival

Timepoint
One year after transplantation

Method of measurement
Examination and following treatment

2

Description
One year disease free survival

Timepoint
One year after transplantation

Method of measurement
Examination and following treatment

3

Description
Rate of chronic GVHD

Timepoint
One year after transplantation

Method of measurement
Examination and following treatment

4

Description
Rate of treatment related mortality

Timepoint
One year after transplantation

Method of measurement
Examination and following treatment

5

Description
Rate of acute GVHD

Timepoint

Three month after transplantation

Method of measurement

Examination and following treatment

Intervention groups

1

Description

Donor lymphocyte infusion (DLI) from donor after subcutaneous granulocyte colony-stimulating factor (G-CSF) at day +30 with average cell dose 4×10^8 mononuclear cells (MNC)/kg (2.5-6×10^8 MNC/kg)

Category

Treatment - Drugs

2

Description

Cyclophosphamide 50 mg/kg at day +3

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Hematology-Oncology & SCT Research Center

Full name of responsible person

Street address

Shariati Hospital, Kargar Ave

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Hematology-Oncology & SCT Research Center

Full name of responsible person

Dr Kamran Alimoghaddam

Street address

Shariati Hospital, Kargar Ave

City

Tehran

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Hematology-Oncology & SCT Research Center

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

Hematology-Oncology & SCT Research Center

Full name of responsible person

Masoud Fakharian

Position

Fellowship of Hematology,Oncology/MD

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Hematology-Oncology & SCT Research Center

Full name of responsible person

Masoud Fakharian

Position

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Other areas of specialty/work

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Person responsible for updating data

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Mahdi Jalili

Position

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Other areas of specialty/work

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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