Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Efficacy of Prophylactic Oral Eltrombopag for Promoting Platelet and Neutrophil Engraftment After Haploidentical Hematopoietic Stem Cell Transplantation in Patients with acute lymphoblastic leukemia: A Phase II Non Randomized-controlled Trial

Protocol summary

Study aim
Studying the effect of prophylactic oral Eltrombopag administration after haploidentical Hematopoietic-Stem-Cell-Transplantation on platelet and neutrophil engraftment

Design
Phase II clinical trial with a historical control group, non-randomized, and open-label

Settings and conduct
This study will be conducted as a phase II, non-randomized, open-label clinical trial with a historical control group at the Hematology, Oncology, and Cell Therapy Research Center. Patients with acute leukemias who undergo haploidentical bone marrow transplantation at this center and meet the eligibility criteria will be enrolled. The outcomes of interest will be compared with those of the historical control group.

Participants/Inclusion and exclusion criteria
Inclusion: Definitive diagnosis of acute lymphocytic leukemia, medical indication of haploidentical hematopoietic stem cell transplantation, the patient must be in complete remission before the transplant. Exclusion: patients with abnormal liver function tests such as alanine aminotransferase greater equal than 2.5 times the upper limit of normal or bilirubin greater than1 mg/dL will not enter the study.

Intervention groups
Intervention: Patients in this group will receive prophylactic oral Eltrombopag, purchased from Nano Darou Company, a thrombopoietin receptor agonist to promote engrafment, at a daily dose of 150–300 mg, starting from the fifth day after transplantation and continuing daily until engraftment for a minimum of 10 days. Historical Control Group: Patients in this group will receive standard conditioning regimen drugs without any engraftment-promoting medication.

Main outcome variables
Platelet engraftment; Neutrophil engraftment; Overall survival ; Relapse; Progression-free-survival ; Cytomegalovirus (CMV) reactivation

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20140818018842N51**
Registration date: **2025-12-12, 1404/09/21**
Registration timing: **registered_while_recruiting**

Last update: **2025-12-12, 1404/09/21**
Update count: **0**

Registration date
2025-12-12, 1404/09/21

Registrant information

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Recruitment status
recruiting

Funding source

Expected recruitment start date

2025-10-23, 1404/08/01

Expected recruitment end date

2027-10-23, 1406/08/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Efficacy of Prophylactic Oral Eltrombopag for Promoting Platelet and Neutrophil Engraftment After Haploidentical Hematopoietic Stem Cell Transplantation in Patients with acute lymphoblastic leukemia: A Phase II Non Randomized-controlled Trial

Public title

Does Eltrombopag Improve Blood Cell Recovery in Leukemia Patients After Transplant?

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Definitive diagnosis of acute lymphocytic leukemia Medical indication of Haploidentical Hematopoietic Stem Cell Transplantation The patient must be in Complete Remission before the transplant

Exclusion criteria:

Patients with abnormal liver function tests such as alanine aminotransferase greater equal than 2.5 times the upper limit of normal or bilirubin greater than1 mg/dL will not enter the study.

Age

No age limit

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

Not 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

Research Ethics Committees of Research Institute for Oncology, Hematology and Cell Therapy - Tehran

Street address

Research Institute for Oncology, Hematology and Cell Therapy, Shariati Hospital, North Kargar Street, Jalal Al-Ahmad Intersection, Tehran

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Approval date

2025-06-02, 1404/03/12

Ethics committee reference number

IR.TUMS.HORCSCT.REC.1404.017

Health conditions studied

1

Description of health condition studied

Acute lymphoblastic leukemia [ALL]

ICD-10 code

C91.0

ICD-10 code description

Acute lymphoblastic leukemia [ALL]

Primary outcomes

1

Description

Platelet engraftment (when the patient is independent of platelet transfusion for at least 7 days with a platelet count >20 × 10^9/L)

Timepoint

Daily measurements, from the start of the intervention and at least until 10 days after the intervention.

Method of measurement

According to the complete blood count (CBC) laboratory test performed using an automated cell counter.

2

Description

Neutrophil engraftment (when the absolute neutrophil count consistently exceeds 0.5 × (10)9/L for 3 days in a row without a growth factor support.)

Timepoint

Daily measurements, from the start of the intervention and at least until 10 days after the intervention.

Method of measurement

According to the complete blood count (CBC) laboratory test performed using an automated cell counter.

3

Description
The occurrence of Graft versus Host disease according to the MAGIC criteria
Timepoint
Daily assessments , from 5 days before the start of the intervention (from the day of transplantation) and until 3 months after the intervention.
Method of measurement
In accordance with the Mount Sinai Acute GVHD International Consortium (MAGIC) criteria

4

Description
Overall survival
Timepoint
Patients will be followed from 5 days before the start of the intervention daily during hospitalization and then monthly after discharge and until 2 years after the intervention
Method of measurement
Survival data will be collected using a checklist that includes survival status and time of assessment by trained personnel during hospitalization in the ward and during post-discharge follow-ups.

5

Description
Relapse
Timepoint
Patients will be followed from 5 days before the start of the intervention daily during hospitalization and then monthly after discharge and until 2 years after the intervention
Method of measurement
Relapse data will be collected using a checklist that includes relapse status and time of assessment by trained personnel during hospitalization in the ward and during post-discharge follow-ups according to patients clinical records.

6

Description
Progression Free survival
Timepoint
Patients will be followed from 5 days before the start of the intervention daily during hospitalization and then monthly after discharge and until 2 years after the intervention
Method of measurement
Survival and relapse data will be collected using a checklist that includes survival and relapse status and time of assessment by trained personnel during hospitalization in the ward and during post-discharge follow-ups according to patients clinical records.

7

Description
Cytomegalovirus (CMV) reactivation
Timepoint
Weekly assessments , from 5 days before the start of the intervention (from the day of transplantation) and until 3 months after the intervention.
Method of measurement
Polymerase chain reaction (PCR) lab test

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Patient with acute leukemia and recipient of haploidentical transplant will receive oral Eltrombopag, which is a thrombopoietin receptor agonist and will be used to promote post- allogenic-hematopoietic-stem-cell-transplantation engraftment, at a daily dose of 150–300 mg starting from fifth day after transplantation and continuing daily until engraftment. Each patient will receive Eltrombopag for a minimum of 10 days, regardless of whether engraftment occurs before day 10 of Eltrombopag therapy. Patients must receive at least 10 consecutive days of Eltrombopag in order to be included in the final analysis. As a safety rule, if the patient’s platelet count reaches or exceeds 500,000 per µL after 10 days, at any point during treatment, Eltrombopag must be discontinued. The eltrombopag used in this study will be purchased from Nano Darou Pharmaceutical Company.
Category
Treatment - Drugs

2

Description
Historical control patients will include patients with acute leukemia who received a haploidentical transplant and did not receive any medication to promote engraftment.
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Cell Therapy and Hematopoietic Stem Cell Transplantation Research Center
Full name of responsible person
Tahereh Rostami
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Sponsors / Funding sources

1

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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
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD
No more information available.

Study Protocol
No - There is not a plan to make this available

Statistical Analysis Plan
No - There is not a plan to make this available

Informed Consent Form
No - There is not a plan to make this available

Clinical Study Report
No - There is not a plan to make this available

Analytic Code
Not applicable

Data Dictionary
No - There is not a plan to make this available