Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Comparison of Myeloablative versus Reduced-Intensity conditioning regimen before Hematopoietic Cell Transplantation in Measurable Residual Disease negative, 50 years or older patients with Acute Myeloid Leukemia, Myelodysplastic Syndromes and Acute Lymphoblastic Leukemia: A phase III Randomized Controlled Trial.

Protocol summary

Study aim
Comparison of overall and disease-free survival in "minimal residual disease"-negative leukemia patients receiving a reduced-intensity regimen versus myeloablative regimen as conditioning regimen before hematopoietic stem cell transplantation.

Design
A phase 3 randomized controlled clinical trial, with 2 parallel groups, on 84 patients. For randomization, a balanced block randomization list will be used.

Settings and conduct
Leukemia patients candidates for allogeneic transplantation in the research institute of Oncology, Hematology and Cell Therapy who are eligible are randomly divided into two groups before transplantation, 1st group receives a reduced intensity conditioning regimen and 2nd group receives a myeloablative regimen before hematopoietic stem cell transplantation. After 1, 3, 6 and 12 months, flow cytometry will be performed to evaluate the minimal residual disease.

Participants/Inclusion and exclusion criteria
Inclusion Criteria: Patients from 50 to 65 years old, leukemia patients who are Measurable Residual Disease negative pre-transplant, patient and donor are allowed to be a full match (8/8), acceptable organ function
Exclusion Criteria: prior allogeneic stem cell transplantation, Karnofsky Performance Score < 70, patients with uncontrolled bacterial, viral or fungal infection

Intervention groups
Intervention group: (Reduced intensity) Fludarabine (ACTOVERCO): 30 mg/m2/day day -6 to -2 (before transplantation) and Busulfan (Nanoalvand): 3.2 mg/kg/day IV day -5 to -4; Control group: (Myeloablative) Busulfan: 3.2 mg/kg/day IV day -6 to -3 and Cyclophosphamide (Baxter): 60 mg/kg/day IV day -2 to -1 (before transplantation)

Main outcome variables
18-month overall survival, disease free survival

General information

Reason for update

Acronym
-

IRCT registration information
IRCT registration number: **IRCT20140818018842N25**
Registration date: **2022-09-01, 1401/06/10**
Registration timing: **registered_while_recruiting**

Last update: **2022-09-01, 1401/06/10**
Update count: **0**

Registration date
2022-09-01, 1401/06/10

Registrant information

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Name of organization / entity
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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-04-04, 1401/01/15
Expected recruitment end date
2023-04-04, 1402/01/15
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison of Myeloablative versus Reduced-Intensity conditioning regimen before Hematopoietic Cell Transplantation in Measurable Residual Disease negative, 50 years or older patients with Acute Myeloid Leukemia, Myelodysplastic Syndromes and Acute Lymphoblastic Leukemia: A phase III Randomized Controlled Trial.

Public title
Comparison of conditioning regimens before Hematopoietic Cell Transplantation in patients with Acute Leukemia.
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Patients from 50 to 65 years old Patients with diagnosis of Myelodysplastic Syndromes , Acute Myeloid Leukemia and Acute Lymphoblastic Leukemia who are Measurable Residual Disease negative pre-transplant within 30 days of enrollment. Patient and donor are allowed to be a full match (8/8), or at least Human Leukocyte Antigens (HLA)-A, -B, -C and DRB1 matched. Cardiac function: Ejection Fraction ≥ 40% Hepatic function: total bilirubin and Aspartate transaminase (AST) and alanine aminotransferase (ALT) ≤ 2,5 x the upper limit of normal Pulmonary function: Forced expiratory volume (FEV1) ≥ 50% Renal function: creatinine clearance > 40 mL/min based on the Cockroft-Gault formula Hematopoietic Cell Transplantation-specific Comorbidity Index (HCT-CI) score <4 Signed informed consent.
Exclusion criteria:
Prior allogeneic stem cell transplantation Symptomatic coronary artery disease Karnofsky Performance Score < 70 Central nervous system involvement Patients with uncontrolled bacterial, viral or fungal infection Females who are pregnant or breastfeeding. Patients seropositive for human immunodeficiency virus.
Age
From **50 years** old to **65 years** old
Gender
Both

Phase
3
Groups that have been masked
No information
Sample size
Target sample size: **84**
Randomization (investigator's opinion)
Randomized
Randomization description
Assigning to the study groups is parallel; group 1 is considered the intervention group which will receive the reduced intensity conditioning regimen, and group 2 is the control group which will receive the myeloablative regimen. The balanced block randomization list will be generated through the research institute's web-based software; after entering the sample size 84 and considering the block size of 4, according to this balanced block randomization list, a sequence of numbers is created, and this sequence of numbers is defined in the system. If the patients meet the criteria of the study after obtaining informed consent, their national code will be entered into the system, and the software will announce the code of each patient.
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
Ethic committee of Hematology- Oncology and cell therapy Research Institute, Tehran University of Me
Street address
Shariati Hospital, Jalal-e-Al-e-Ahmad Hwy
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Postal code
1411713135
Approval date
2022-03-15, 1400/12/24
Ethics committee reference number
IR.TUMS.HORCSCT.REC.1400.036

Health conditions studied

1

Description of health condition studied
Acute Myeloblastic leukemia
ICD-10 code
C92.0
ICD-10 code description
Acute myeloblastic leukemia

2

Description of health condition studied
Myelodysplastic Syndromes
ICD-10 code
D46
ICD-10 code description
Myelodysplastic syndromes

3

Description of health condition studied
Acute Lymphoblastic Leukemia
ICD-10 code
C91.0
ICD-10 code description
Acute lymphoblastic leukemia [ALL]

Primary outcomes

1

Description
overall survival
Timepoint
Monthly for 18 months after transplantation
Method of measurement
Visiting the patient and performing monthly lab tests in outpatient clinique

Secondary outcomes

1

Description
Disease Free survival after transplantation
Timepoint
1, 3, 6, 9, 12 and 18 months post transplant
Method of measurement
Bone marrow biopsy and aspiration and flowcytometry and chimerism.

2

Description
Transplant Related Mortality
Timepoint
Monthly for 18 months after transplantation
Method of measurement
Visiting the patient in person and performing monthly lab tests in outpatient clinique

3

Description
Incidence of acute graft versus host disease
Timepoint
Monthly for 4 months after transplantation
Method of measurement
Visiting the patient in person and performing monthly lab tests in outpatient clinique

4

Description
Incidence of chronic graft versus host disease
Timepoint
Monthly for 18 months after transplantation
Method of measurement
Visiting the patient in person and performing monthly lab tests in outpatient clinique

5

Description
Relapse Incidence
Timepoint
1, 3, 6, 9, 12 and 18 months post transplant
Method of measurement
Bone marrow biopsy and aspiration and flowcytometry and chimerism.

6

Description
Incidence of infectious complications post-transplant
Timepoint
Monthly for 18 months after transplantation
Method of measurement
Visiting the patient in person and performing monthly lab tests in outpatient clinique

Intervention groups

1

Description
Intervention group: patients with acute leukemia who are candidates for allogeneic Hematopoietic Cell Transplantation and are between 50-65 years old and Measurable Residual Disease negative will be included in the trial. After randomization, they will be transplanted according to the reduced-intensity conditioning regimen. Reduced-intensity conditioning regimen consists of: Fludarabine (ACTOVERCO): 30 mg/m2/day day -6 to -2 before transplantation and Busulfan (Nanoalvand): 3.2 mg/kg/day, from day -5 to -4 before transplantation.
Category
Treatment - Other

2

Description
Control group: patients with acute leukemia who are candidates for allogeneic Hematopoietic Cell Transplantation and are between 50-65 years and Measurable Residual Disease negative will be included in the trial. After randomization, they will be transplanted according to the myeloablative conditioning regimen. Myeloablative conditioning regimen consists of: Busulfan (Nanoalvand): 3.2 mg/kg/day, from day -6 to -3 and Cyclophosphamide (Baxter): 60 mg/kg/day, from day -2 to -1 before transplantation.
Category
Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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Full name of responsible person
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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

Name of organization / entity
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Position
Research Assistant

Latest degree
Master

Other areas of specialty/work
Epidemiology

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