

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

05 Jun 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/m<sup>2</sup>/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

##### Name

Leyla Sharifi Aliabadi

##### Name of organization / entity

Research Institute for Hematology, Oncology and Stem Cell Transplantation, Tehran University of Medic

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 8490 3691

##### Email address

ctu@sina.tums.ac.ir

##### 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  $\geq$  40% Hepatic function: total bilirubin and Aspartate transaminase (AST) and alanine aminotransferase (ALT)  $\leq$  2,5 x the upper limit of normal Pulmonary function: Forced expiratory volume (FEV1)  $\geq$  50% Renal function: creatinine clearance  $>$  40 mL/min based on the Cockcroft-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

##### City

Tehran

##### Province

Tehran

##### 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 clinic

## **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 clinic

### 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 clinic

## 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 clinic

## 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 clinic

## **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/m<sup>2</sup>/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**

Research Institute for Oncology, Hematology and Cell Therapy, Tehran University of Medical Sciences

**Full name of responsible person**

Tanaz Sayar Bahri

**Street address**

Shariati Hospital, Jalal-e-Al-e-Ahmad Hwy

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## Sponsors / Funding sources

1

### Sponsor

**Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

Dr. Akbar Fotouhi

**Street address**

Poursina St., 16 Azar St., Keshavarz Blvd.

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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**

Tehran University of Medical Sciences

**Full name of responsible person**

Leyla Sharifi Aliabadi

**Position**

Research Assistant

**Latest degree**

Master

**Other areas of specialty/work**

Epidemiology

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## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

Tanaz Sayar Bahri

**Position**

Assistant professor

**Latest degree**

Subspecialist

**Other areas of specialty/work**

Hematology

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## Person responsible for updating data

### Contact

**Name of organization / entity**

Tehran University of Medical Sciences

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**Other areas of specialty/work**

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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