

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Safety and efficacy of allogeneic natural killer cells therapy in acute myeloid leukemia (other than M3) patients transplanted with allogeneic hematopoietic stem cell

#### Protocol summary

##### Study aim

Primary evaluation of allogeneic haplo-identical natural killer cell therapy given by apparently healthy volunteer donors (third party donor) in patients with acute myeloid leukemia (Non-M3) transplanted with allogeneic hematopoietic stem cells.

##### Design

Un-randomized, open-labeled Sample size: 12, taking into account the loss: 15 Phase I and II

##### Settings and conduct

NK cell therapy in acute myeloid leukemia (non-M3) patients in Taleghani Hospital. Donor leukopheresis is performed without mobilization. NK cells are carried out using the Milteney CD56+ enrichment kit. The isolated NK cells will be injected into the patients and its safety and efficiency will be evaluated in a period of six months.

##### Participants/Inclusion and exclusion criteria

En Patients with acute myeloid leukemia (other than M3) confirmed by peripheral blood and bone marrow morphology, and flow cytometry and molecular assessments History of transplantation with compatible allogeneic hematopoietic stem cells Kanofsky index above 70% Expected survival of more than six months Absence of other confirmed malignancies Entering the second complete remission phase (recovery of patients after the first recurrence) High risk-patients with negative or positive minimal residual disease

##### Intervention groups

Single group

##### Main outcome variables

Adverse effects, Overall survival, and Response to treatment based on criteria defined by the IMWG

#### General information

##### Reason for update

##### Acronym

#### IRCT registration information

IRCT registration number: **IRCT20230801058996N2**

Registration date: **2023-09-10, 1402/06/19**

Registration timing: **registered\_while\_recruiting**

Last update: **2023-09-10, 1402/06/19**

Update count: **0**

#### Registration date

2023-09-10, 1402/06/19

#### Registrant information

##### Name

Elham Roshandel

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 5798 4000

##### Email address

elham.roshandel@sbmu.ac.ir

#### Recruitment status

**Recruitment complete**

#### Funding source

#### Expected recruitment start date

2023-08-22, 1402/05/31

#### Expected recruitment end date

2024-08-21, 1403/05/31

#### Actual recruitment start date

empty

#### Actual recruitment end date

empty

#### Trial completion date

empty

#### Scientific title

Safety and efficacy of allogeneic natural killer cells therapy in acute myeloid leukemia (other than M3)

patients transplanted with allogeneic hematopoietic stem cell

#### Public title

Natural killer cell therapy in acute myeloid leukemia patients

#### Purpose

Treatment

#### Inclusion/Exclusion criteria

##### Inclusion criteria:

Patients with acute myeloid leukemia (other than M3) confirmed by peripheral blood and bone marrow morphology, and flow cytometry and molecular assessments History of transplantation with compatible allogeneic hematopoietic stem cells Kanofsky index above 70% Expected survival of more than six months Absence of other confirmed malignancies Entering the second complete remission phase (recovery of patients after the first recurrence) High risk-patients with negative or positive minimal residual disease

##### Exclusion criteria:

Patients with acute myeloid leukemia-M3 Central nervous system involvement with leukemic cells in the last 3 months

#### Age

From **12 years** old to **80 years** old

#### Gender

Both

#### Phase

1-2

#### Groups that have been masked

*No information*

#### Sample size

Target sample size: **15**

#### 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

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee of Shahid Beheshti University of medical Sciences

##### Street address

Taleghani Hospital, Aarabi street, Yaman street, Chamran highway

##### City

Tehran

#### Province

Tehran

#### Postal code

۱۹۸۵۷۱۱۱۵۱

#### Approval date

2023-08-12, 1402/05/21

#### Ethics committee reference number

IR.SBMU.REC.1402.006

## Health conditions studied

### 1

#### Description of health condition studied

Acute myeloid leukemia

#### ICD-10 code

C92.0

#### ICD-10 code description

Acute myeloblastic leukaemia

## Primary outcomes

### 1

#### Description

The percentage of patients who show adverse effects during or after NK cell therapy.

#### Timepoint

From the first dose of NK cells infusion until six months after its last dose.

#### Method of measurement

The patient's statements and the medical team's examinations during the patient's regular visits to the bone marrow transplantation clinic for follow-up.

### 2

#### Description

Overall survival in patients after NK cell therapy

#### Timepoint

From the first dose of NK cells infusion until six months after its last dose.

#### Method of measurement

Regular patient visits to bone marrow transplantation clinic for follow-up and regular telephone monitoring of patients.

### 3

#### Description

Response to treatment based on criteria defined by the International Multiple Myeloma Working Group

#### Timepoint

From the first dose of NK cells infusion until six months after its last dose.

#### Method of measurement

Regular patient examination in bone marrow transplantation clinic for follow-up and based on criteria defined by the International Multiple Myeloma Working Group

## Secondary outcomes

### 1

#### Description

Evaluation of "Event Free Survival" in a six month period

#### Timepoint

From the first dose of NK cells infusion until six months after its last dose

#### Method of measurement

Regular patient visits to bone marrow transplantation clinic for follow-up and regular telephone monitoring of patients.

### 2

#### Description

Evaluation of "Progression free survival" in a six month period

#### Timepoint

From the first dose of NK cells infusion until six months after its last dose

#### Method of measurement

Regular patient visits to bone marrow transplantation clinic for follow-up and regular telephone monitoring of patients.

### 3

#### Description

Evaluation of "non-relapse mortality" in a six month period

#### Timepoint

From the first dose of NK cells infusion until six months after its last dose

#### Method of measurement

Regular patient visits to bone marrow transplantation clinic for follow-up and regular telephone monitoring of patients.

### 4

#### Description

Evaluation of "Overall survival" in a six month period

#### Timepoint

From the first dose of NK cells infusion until six months after its last dose

#### Method of measurement

Regular patient visits to bone marrow transplantation clinic for follow-up and regular telephone monitoring of patients.

### 5

#### Description

Evaluation of "graft versus host disease" in a six month period

#### Timepoint

From the first dose of NK cells infusion until six months after its last dose

#### Method of measurement

Regular patient visits to bone marrow transplantation clinic for follow-up and regular telephone monitoring of

patients.

## Intervention groups

### 1

#### Description

Intervention group: Allogeneic natural killer cell therapy

#### Category

Treatment - Other

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Taleghani Hospital

##### Full name of responsible person

Elham Roshandel

##### Street address

Taleghani Hospital, Aarabi street, Yaman street, Chamran highway

##### City

Tehran

##### Province

Tehran

##### Postal code

۱۹۸۵۷۱۱۱۵۱

##### Phone

+98 21 2303 1658

##### Fax

+98 21 2303 1658

##### Email

info@sbmu.ac.ir

##### Web page address

<https://taleghani.sbmu.ac.ir/>

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Shahid Beheshti University of Medical Sciences

##### Full name of responsible person

Afshin Zarghi

##### Street address

Shahid Beheshti University of Medical Sciences, Aarabi street, Daneshjou Boulevard, Velenjak

##### City

Tehran

##### Province

Tehran

##### Postal code

1985717443

##### Phone

+98 21 2243 9872

##### Fax

+98 21 2243 9872

##### Email

info@sbmu.ac.ir

**Web page address**

https://sbmu.ac.ir/

**Grant name**

**Grant code / Reference number**

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

No

**Title of funding source**

Javidan Motaher Charity Foundation of Tehran

**Proportion provided by this source**

50

**Public or private sector**

Private

**Domestic or foreign origin**

Domestic

**Category of foreign source of funding**

empty

**Country of origin**

**Type of organization providing the funding**

Other

**2**

**Sponsor**

**Name of organization / entity**

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Afshin zarghi

**Street address**

Shahid Beheshti University of Medical Sciences,  
Aarabi street, Daneshjou Boulevard, Velenjak

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**Grant name**

**Grant code / Reference number**

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

No

**Title of funding source**

Pharmed Behin Azma

**Proportion provided by this source**

50

**Public or private sector**

Private

**Domestic or foreign origin**

Domestic

**Category of foreign source of funding**

empty

**Country of origin**

**Type of organization providing the funding**

Other

**Person responsible for general inquiries**

**Contact**

**Name of organization / entity**

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Elham Roshandel

**Position**

Associate professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Cell Therapy

**Street address**

Taleghani Hospital, Aarabi street, Yaman street,  
Chamran highway

**City**

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**Province**

Tehran

**Postal code**

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**Phone**

+98 21 2303 1658

**Fax**

+98 21 2303 1658

**Email**

elham.roshandel@gmail.com

**Person responsible for scientific inquiries**

**Contact**

**Name of organization / entity**

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Elham Roshandel

**Position**

Associate professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

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**Email**

elham.roshandel@gmail.com

## Person responsible for updating data

### Contact

**Name of organization / entity**

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Elham Roshandel

**Position**

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**Latest degree**

Ph.D.

**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**

Due to the confidentiality of patient information

**Study Protocol**

Yes - There is a plan to make this available

**Statistical Analysis Plan**

Yes - There is a plan to make this available

**Informed Consent Form**

Yes - There is a plan to make this available

**Clinical Study Report**

Yes - There is a plan to make this available

**Analytic Code**

Not applicable

**Data Dictionary**

Not applicable

**Title and more details about the data/document**

Bone marrow and blood test results (CBC, liver and kidney tests) before the first injection as well as before and after each NK cell injection; Chimerism 30 days after transplantation; NK cell count 40 days after the intervention; Immune cells (types of lymphocytes and NK cells) before the first dose of NK cell and 90 days after the intervention; Bone marrow assessment two, four and six months after the intervention; Adverse effects during and after the intervention; Survival during the six months period after the bone marrow transplantation. All potential patient data can be shared after de-identifying them.

**When the data will become available and for how long**

Data files would be accessible after publication.

**To whom data/document is available**

Data files would be accessible to both academic researchers and industrial developers.

**Under which criteria data/document could be used**

Access to the data file will be provided for academic researchers to study. Data analysis is possible for use in meta-analysis review articles. Authentication of the applicant and provision of an academic email is required to access the data file.

**From where data/document is obtainable**

To receive the data file, please refer to the person in charge of the trial (Dr. Elham Roshandel): E-mail: elham.roshandel@gmail.com Phone number: 00982123031658 Address: Hematopoietic stem cell research center, Yas administrative complex, 4th floor, Taleghani Hospital, Aarabi street, Yaman street, Chamran highway, Tehran.

**What processes are involved for a request to access data/document**

The applicant must state his/her request accurately and completely. The requested data will be provided within ten working days after receiving the request.

**Comments**