

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 2026

Safety and efficacy of cell therapy with allogeneic natural killer cells activated with interleukin 2 and 15 in patients with refractory non-M3 acute myeloid leukemia (absence of hematological, morphological or molecular response after at least two treatment regimens)

Protocol summary

Study aim

Safety and efficacy of cell therapy with allogeneic natural killer cells activated with interleukin 2 and 15 in patients with acute myeloid leukemia (non-M3) to negate the minimal residual disease.

Design

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

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. Isolated NK cells are activated using interleukin 2 and 15. The activated NK cells will be injected into the patients and its safety and efficiency as well as minimal residual disease will be evaluated in a period of six months.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients with acute myeloid leukemia(non-M3) diagnosed according to the World Health Organization classification; Inadequate response to induction therapy (incomplete or complete remission with minimal positive residual disease);Relapse (hematologic, morphologic or positive minimal residual disease); Karnofsky index above 70% Exclusion criteria: Patients with acute myeloid leukemia-M3; Patients with low-risk acute myeloid leukemia; Patients in complete molecular remission

Intervention groups

Single group, Cell therapy with allogeneic natural killer cells activated with interleukin 2 and 15

Main outcome variables

The percentage of patients who show adverse effects during or after NK cell therapy. Overall survival in patients after NK cell therapy. Response to treatment (complete remission based on hematologic, morphologic

and molecular assessments)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230801058996N3**

Registration date: **2023-10-07, 1402/07/15**

Registration timing: **registered_while_recruiting**

Last update: **2023-10-07, 1402/07/15**

Update count: **0**

Registration date

2023-10-07, 1402/07/15

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

2023-09-22, 1402/06/31

Expected recruitment end date

2024-09-21, 1403/06/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Safety and efficacy of cell therapy with allogeneic natural killer cells activated with interleukin 2 and 15 in patients with refractory non-M3 acute myeloid leukemia (absence of hematological, morphological or molecular response after at least two treatment regimens)

Public title

Activated NK cell therapy to negate MRD in AML patients

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Patients with acute myeloid leukemia(non-M3) diagnosed according to the World Health Organization classification Inadequate response to induction therapy (incomplete or complete remission with minimal positive residual disease) Relapse (Hematologic, morphologic or positive minimal residual disease) Karnofsky index above 70%

Exclusion criteria:

Patients with acute myeloid leukemia-M3 Patients with low-risk acute myeloid leukemia Patients in complete molecular remission

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

2023-07-01, 1402/04/10

Ethics committee reference number

IR.SBMU.RETECH.REC.1402.153

Health conditions studied**1****Description of health condition studied**

Acute myeloid leukemia

ICD-10 code

C92.0

ICD-10 code description

Acute myeloblastic leukemia

Primary outcomes**1****Description**

The percentage of 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**

Response to treatment (Based on hematologic, morphologic and molecular assessments).

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

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.

Intervention groups

1

Description

Intervention group: patients with acute myeloid leukemia (other than M3) undergo cell therapy with allogeneic natural killer cells activated with interleukin 2 and 15. First, the allogeneic donor is undergo apheresis to isolate mononuclear cells. Then the NK cells are enriched from the apheresis product using the CliniMacs device. These cells are incubated overnight with interleukin 2 and 15 to activate. Activated cells are injected into patients in three incremental doses of one, three, and five million cells per kilogram of body weight, respectively.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Taleghani Hospital

Full name of responsible person

Elham Roshandel

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Taleghani Hospital, Aarabi street, Yaman street, Chamran highway

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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

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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

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

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Web page address

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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 addressTaleghani Hospital, Aarabi street, Yaman street,
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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

Cell therapy

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Shahid Beheshti University of Medical Sciences

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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

Diagnosis: based on peripheral blood and bone marrow morphology, immunophenotyping, karyotype, and molecular tests. Treatment: chemotherapy, immunotherapy and hematopoietic cell transplantation. The results of peripheral blood and bone marrow tests, flow cytometry, polymerase chain reaction and minimal residual disease before the intervention, after the last intervention, and on the 90th day after the intervention. 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