Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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 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
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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
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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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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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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

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

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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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Person responsible for updating data

Contact

Name of organization / entity
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
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