Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Safety and efficiency of allogenic natural killer cell therapy in relapsed/refractory multiple myeloma and high-risk multiple myeloma patients

Protocol summary

Study aim
Safety and efficiency of allogenic natural killer cell therapy in relapsed/refractory multiple myeloma and high-risk multiple myeloma patients

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 relapsed/refractory and high-risk multiple myeloma 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
Inclusion criteria: At least one of the followings: more than 0.5g/dl M-protein in serum protein electrophoresis, urine excretion of at least 200mg of M-protein, more than 10mg/dL immunoglobulin free light chain in serum Relapse based on International Myeloma Working Group Treatment refractory High-risk multiple myeloma according to the IMWG or the presence of any of the high-risk cytogenetic cases Exclusion criteria: Insufficient engraftment Total bilirubin and Creatinine greater than 2mg/dL Renal clearance less than 30mL/min Liver enzymes more than 2.5 times the upper limit

Intervention groups
Single group

Main outcome variables
Percentage of adverse effect Overall survival Response to treatment based on criteria defined by the IMWG

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20230801058996N1**
Registration date: **2023-08-30, 1402/06/08**
Registration timing: **registered_while_recruiting**

Last update: **2023-08-30, 1402/06/08**
Update count: **0**

Registration date
2023-08-30, 1402/06/08

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
2023-01-22, 1401/11/02

Expected recruitment end date
2024-03-17, 1402/12/27

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Safety and efficiency of allogenic natural killer cell therapy in relapsed/refractory multiple myeloma and

high-risk multiple myeloma patients

Public title
Allogeneic natural killer cell therapy in multiple myeloma patients
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
The presence of at least one of the followings: more than 0.5 g/dl M-protein in serum protein electrophoresis, excretion of at least 200 mg of M-protein in urine, more than 10 mg/dL immunoglobulin free light chain in serum Relapse confirmation based on International Myeloma Working Group Refractory to at least two treatment regimens (an immunomodulatory drug, a proteasome inhibitor drug) High-risk multiple myeloma according to the International Myeloma Working Group: "recurrence within 12 months after the previous autologous transplant or progression of the disease within 1 year since the diagnosis of the disease" or "the presence of any of the high-risk cytogenetic cases including t(4;14), t (14;16), (14;20)t, chromosome gain/amplification (+1q21), deletion of the short arm of chromosome 17 (del(17p))"
Exclusion criteria:
Insufficiency of engraftment parameters: WBC less than1000/µl, Platelets less than 20000/µl, Hemoglobin less than 8g/dL Total bilirubin greater than 2mg/dL Creatinine greater than 2mg/dL Renal clearance less than 30 mL/min Liver enzymes more than 2.5 times the upper limit of normal
Age
From **18 years** old to **70 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
2023-01-22, 1401/11/02
Ethics committee reference number
IR.SBMU.REC.1401.029

Health conditions studied

1

Description of health condition studied
Multiple myeloma
ICD-10 code
C90.0
ICD-10 code description
Multiple myeloma

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 (IMWG)

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 (IMWG)

Secondary outcomes

empty

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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Phone
+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
Taleghani Hospital, Aarabi street, Yaman street, Chamran highway
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Email
info@sbmu.ac.ir
Web page address
https://taleghani.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
Taleghani Hospital, Aarabi street, Yaman street, Chamran highway
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Email
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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
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Taleghani Hospital, Aarabi street, Yaman street, Chamran highway
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Person responsible for scientific inquiries

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Person responsible for updating data

Contact
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Position
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Other areas of specialty/work
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elham.roshandel@gmail.com

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
No - There is not 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 CRAB, FISH, serum and urine M-protein, immunoglobulin free light chain, and percentage of bone marrow plasma cells), treatment process (chemotherapy, immunomodulatory or proteasome inhibitor drugs, and stem cell transplantation) before the intervention, the assessments results (blood and bone marrow hematology tests, liver and kidney tests, immunofixation, immunoglobulin light chain and electrophoresis of urine and serum proteins) before the intervention, after the last intervention, and six months 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