Clinical Trial Protocol
Iranian Registry of Clinical Trials

02 Jul 2026

Evaluation of efficacy and safety of allogeneic activated Natural Killer cells in adult patients with relapsed/refractory acute myeloid leukemia.

Protocol summary

Study aim

1. Safety evaluation (tolerability of adverse effects) of intravenous injection of allogeneic natural killer cells to adult patients with relapsed/refractory acute myeloid leukemia 2. Evaluating the effectiveness of treatment (induction of GVL effect) of allogeneic natural killer cells in adult patients with relapsed/refractory acute myeloid leukemia.

Design

Phase 2 clinical trial without control group on 5 patients

Settings and conduct

The preparation and injection of the first round of NK is done as soon as entering the study. Injections are done in three times, once a week. Before receiving NK cells, fludarabine and cyclophosphamide are prescribed. NK suspended in 50 ml of 5% albumin solution is injected intravenously (central vein) for 15-20 minutes. In each NK injection, the number of injected live cells is determined based on the patient's weight. The injected NK cell is considered to be at least 106 cells per kilogram of body weight.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 1- Patients with AML of both genders in the age range of 18 to 65 years 2- Patients with known involvement of CNS with AML provided that they have been treated and CSF is clear for at least 2 weeks before enrollment in the study. 3- ECOG functional status less than or equal to 2. 4- Adequate functioning of organs 5- Be able to stop using corticosteroids and other immunosuppressive drugs from the 3rd day of the trial and up to 30 days after the injection of NK cells. 6- Absence of pregnancy or breastfeeding 7- Failure to receive any research drug within 14 days before the start of the clinical trial 8- The ability to understand and the willingness to sign a certified informed consent document (or if there is an authorized legal representative)

Intervention groups

Transfusion of allogenic natural killer cells

Main outcome variables

NK cell; GvHD grade III; ST2; REG3α; S100; TIM3; HGF

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200417047113N2**
Registration date: **2023-01-25, 1401/11/05**
Registration timing: **registered_while_recruiting**

Last update: **2023-01-25, 1401/11/05**
Update count: **0**

Registration date

2023-01-25, 1401/11/05

Registrant information

Name

Sahar Shojaei

Name of organization / entity

Middle East Gene Therapy project

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-12-22, 1401/10/01

Expected recruitment end date

2024-12-21, 1403/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of efficacy and safety of allogeneic activated Natural Killer cells in adult patients with relapsed/refractory acute myeloid leukemia.

Public title

Effect of treatmen with natural killer cells in acute myeloid leukemia

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with AML of both genders in the age range of 18 to 65 years with the following conditions:• Refractory AML that has not fully recovered after induction therapy.• Relapsed AML that is not a candidate for bone marrow allogeneic transplantation.• High-risk AML (based on ELN criteria) in complete remission (CR) but currently not a candidate for allogeneic bone marrow transplantation.• Relapsed AML after bone marrow transplantation Patients with known CNS involvement with AML provided that they had been treated and the CSF was clear for at least 2 weeks prior to study enrollment ECOG performance status less than or equal to 2 Adequate performance of organs as follows:• Total bilirubin ≤ 2 mg/dL• AST(SGOT)/ALT(SGPT) ≤ 3.0 x IULN• Creatinine within normal institutional limits OR creatinine clearance ≥ 50 mL/min/1.73 m2 by Cockcroft-Gault Formula (adults) or Schwartz formula (pediatric cohort)• Oxygen saturation ≥90% on room air• Ejection fraction ≥50% Be able to stop using corticosteroids and other immunosuppressive drugs from day 3- the beginning of the trial and up to 30 days after the injection of NK cells. However, if clinically necessary, the use of low-level corticosteroids is allowed. Low-level corticosteroid use was defined as 10 mg or less of prednisone (or equivalent for other steroids) per day Not pregnant or breastfeeding Failure to receive any research drug within 14 days before the start of the clinical trial Ability to understand and willingness to sign a certified informed consent document (or if there is an authorized legal representative)

Exclusion criteria:

Uncontrolled bacterial or viral infections, or known HIV, hepatitis B or C infection Uncontrolled angina, severe uncontrolled ventricular arrhythmias, or EKG indicating acute ischemia or active conduction system abnormalities New progressive pulmonary infiltrates on screening chest x-ray or chest CT scan that were not evaluated by bronchoscopy. Infiltrations attributed to infection should be stable and improving after 1 week of appropriate therapy (4 weeks for suspected or proven fungal infections) Known sensitivity to one or more study agents Active autoimmune disease that requires systemic immunosuppression treatment Known history of other cancers in the last 5 years

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **5**

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

Vice President of Research and Technology Shahid Beheshti University of Medical Sciences (Research E

Street address

Shahid Beheshti Medical university, Yaman St, Shahid Chamran Highway

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Province

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Postal code

1985717443

Approval date

2021-11-28, 1400/09/07

Ethics committee reference number

IR.SBMU.RETECH.REC.1400.671

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

percentage of peripheral blood blast

Timepoint

Before treatment and then 4,8 and 12 weeks after treatment

Method of measurement

Peripheral blood Flowcytometry

2

Description

Hematologic parameters

Timepoint

before starting the treatment and then weekly until 6 weeks and then monthly

Method of measurement

CBC

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The preparation and injection of the first round of natural killer cells (NK) is done as soon as entering the study. Injections are done in three times, once a week. Before receiving NK cells, fludarabine and cyclophosphamide drugs are prescribed. NK suspended in 63 ml of 6% albumin solution is injected intravenously (central vein) for 16-23 minutes. In each NK injection, the number of injected live cells is determined based on the patient's weight. The injected NK cell is considered to be at least 10 to the power of 6 cells per kilogram of body weight. The number of injected cells is calculated based on the number of living cells.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Taleghani hospital

Full name of responsible person

Sina Salari

Street address

Arabi St, Yaman St, Shahid Chamran highway, Tehran, Iran

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2

Recruitment center

Name of recruitment center

Namazi Hospital

Full name of responsible person

Alireza Rezvani

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3

Recruitment center

Name of recruitment center

Seyedoshohada Hospital

Full name of responsible person

Valiollah Mehrzad

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Nahr farshadi Alley, Khayam St, Isfahan

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Middle East Gene Therapy corporation

Full name of responsible person

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shojaeisahar@gmail.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Middle East Gene Therapy corporation
Proportion provided by this source
100
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
Aida Iranpour
Position
Adult Hematology and Oncology specialist assistant
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
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
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available
Title and more details about the data/document
After de-identifying individuals, a portion of the data that contain information related to the main outcome could be shared
When the data will become available and for how long

Access starts 6 months after the results are published

To whom data/document is available

People related to academic and scientific centers

Under which criteria data/document could be used

In order to write articles or design similar studies

From where data/document is obtainable

By email with the person responsible for the scientific response of the study

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

An answer will be given by e-mail within a period of one month after the review of the request

Comments