Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Phase I/II Clinical Trial (Safety and feasibility) using ex-vivo expanded Haploidentical donor-derived (Natural Killer Cell)-NK Cells against advanced refractory/relapsed Acute Myeloid Leukemia (AML)

Protocol summary

Study aim

Safety and feasibility study of allogeneic ex vivo expanded NK cell therapy against advanced refractory/relapsed AML

Design

Conditioning regimens, including cyclophosphamide at a dose of 20 mg/Kg every day during 2-1 days before injection and fludarabine at a dose of 20 mg/ml every day due to 4-1 days before injection (for three days) would be prescribed to the patient. One day after the completion of the conditioning regimen, 1-5 ×10^6 NK cells/Kg from an allogeneic source which have prepared in the laboratory would be injected due to 1 hour. The second infusion on the 7th day with increasing doses includes 5 -10 million cells per kilogram of body weight would be infused without a conditioning regimen.

Settings and conduct

Receive conditioning regime, intravenous injection of Natural killer cells twice a week apart in hospitals with special cell therapy and transplantation awards

Participants/Inclusion and exclusion criteria

Inclusion Criteria: Drug-resistant AML patients who have not responded to 2 treatment cycles or recurrent cases who are not candidates for routine therapies or bone marrow transplants. The toxicity or side effects of chemotherapy regimens such as severe cytopenia would be assigned and in case of severe symptoms, patients should be excluded from the study. Exclusion Criteria 1- Simultaneously receiving chemotherapy drugs 2- CHF history during the last 6 months (Congestive Heart Failure) 3- USA history during the last 6 months (Unstable Angina) 4 - Active bacterial, fungal, or viral infections in the last month who have reduced the patient's tolerance to a new treatment

Intervention groups

Patient with Drug-resistant acute myeloid leukemia who will receive two dosage NK cells (1-5x10^6 per kg) after conditioning regimen receiving.

Main outcome variables

-No systemic toxicity and allergy reactions in the patients after cell injection -reduction of tumor burden

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200621047859N3**
Registration date: **2020-12-30, 1399/10/10**
Registration timing: **registered_while_recruiting**

Last update: **2020-12-30, 1399/10/10**
Update count: **0**

Registration date

2020-12-30, 1399/10/10

Registrant information

Name

Ramin Sarrami Forooshani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 8879 6003

Email address

rsf1351@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-09-22, 1399/07/01

Expected recruitment end date

2021-12-22, 1400/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Phase I/II Clinical Trial (Safety and feasibility) using ex-vivo expanded Haploidentical donor-derived (Natural Killer Cell)-NK Cells against advanced refractory/relapsed Acute Myeloid Leukemia (AML)

Public title

The Acute Myeloid Leukemia (AML) immune cell therapy using allogeneic ex-vivo expanded Natural Killer Cells (NK cells) transplantation

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

1- Age 18 to 70 years 2. Drug-resistant AML patients with no response to 2 treatments line or recurrent cases that can not be candidates for standard therapies or bone marrow transplants 3- The toxicity of chemotherapy regimens (such as severe cytopenia) should be assigned and it would be checked as a regimen with no significant side effects. 4- PS≥2[Performance Status (PS)] 5- The results of these tests should be available:• [glomerular filtration rate (GFR)] GFR≥60 or CR≥2 mg / dl• ALT <2.5XULN / Bid≤2• O2Sat> 92% in room air• Cardiac classification status (III> NHC) or [ejection fraction]EF> 50%• Negative pregnancy test• Negative HIV testing

Exclusion criteria:

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: **30**

Randomization (investigator's opinion)

Not randomized

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

Research Ethics Committee of Motamed Cancer Institute academic center for education, culture and res

Street address

No146, South Ghandi, Vanaq Square

City

Tehran

Province

Tehran

Postal code

1517964311

Approval date

2019-10-16, 1398/07/24

Ethics committee reference number

IR.ACECR.IBCRC.REC.1398.015

Health conditions studied

1

Description of health condition studied

Acute Myeloid Leukemia (AML)

ICD-10 code

C92.0

ICD-10 code description

Acute myeloblastic leukemia

Primary outcomes

1

Description

Possible symptoms of hyper-sensitivity and allergy after injection

Timepoint

Daily until the third day after the injection and then weekly until the day +90 after the injection

Method of measurement

Using CTCAE check list

2

Description

Decrease of tumor burden

Timepoint

A week after injection and every month until 3 months

Method of measurement

Physical Examination, Flow cytometry, CBC

3

Description

Graft versus host disease (GVHD) symptoms

Timepoint

Daily until the third day after the injection and then weekly until the day +90 after the injection

Method of measurement

Physical examination - Imaging - Laboratory tests

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Patients with acute resistant myeloid leukemia who receive conditioning regimen 3 days before cell therapy then 5-10 million cell per kilogram of patient weight would be infused intravenously one week apart
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Reza Hospital
Full name of responsible person
Dr Mohsen Rajaei nejhad
Street address
West Fatemi avenue, Etemadzade street
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14117 1854
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2

Recruitment center
Name of recruitment center
Shariati hospital
Full name of responsible person
Dr Maryam Barkhordari
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North Kargar St., Jalal Al-Ahmad Intersection, Shariati Hospital
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3

Recruitment center
Name of recruitment center
Dei Hospital
Full name of responsible person
Dr Ardeshir Ghavamzadeh
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Motamed Cancer Institute
Full name of responsible person
Dr Keivan Majidzadeh Ardebili
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K1majidzadeh@gmail.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
Cell therapy budget of the Islamic Consultative Assembly
Proportion provided by this source
10
Public or private sector
Public
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
Modiriat Atiye Bahman Company
Full name of responsible person
Sina Hasnalizadeh
Street address
No-1, Ghasemi, Tabatabaei
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1459973114
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Grant name

Grant code / Reference number

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

Title of funding source
Modiriat Atiye Bahman Company

Proportion provided by this source
90

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
Iranian academic center for education culture and research
Full name of responsible person
Dr Ramin Sarrami Forooshani
Position
Associated Professor
Latest degree
Ph.D.
Other areas of specialty/work
Virology
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Person responsible for scientific inquiries

Contact

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Person responsible for updating data

Contact

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Full name of responsible person
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z.hashemi87@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available

Study Protocol
Undecided - It is not yet known if there will be a plan to

make this available

Statistical Analysis Plan

Not applicable

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Not applicable

Analytic Code

Not applicable

Data Dictionary

Not applicable