

Clinical Trial Protocol

Iranian Registry of Clinical Trials

14 Jul 2026

A Clinical trial to assess the effect of Natural Killer Cell transplantation in treatment of patients with Acute lymphoblastic leukemia (ALL) and chronic lymphocytic leukemia (CLL)

Protocol summary

Summary

One of the most effective methods for boosting innate immune response against cancer is the transfer of natural killer(NK) cells to patients and subsequent activation of these cells with IL-2. In this study, we have one intervention group with 10 people. The purpose of this study is to use these cells to treat cancers, including leukemia. After choosing the appropriate donors who are genetically incompatible in terms of KIR gene, during standard Apheresis, peripheral blood mononuclear cells (PBMCs) are separated from the blood of the donors according to the classic protocol. Several injections of cyclophosphamide and fludarabine chemotherapy drugs will be performed intravenously for 10 patients (CLL & KIR-HLA mismatched donor). Then, the prepared natural killer cells (29 * 10⁶/kg NK) will be injected to the patients. To stimulate the proliferation and activation of NK-positive cells in the patient's body, repetitive doses of IL-2 (6 doses) will be administrated subcutaneously every 48 hours (one day before injection). In order to evaluate the immune system and the status of NK cells in terms of phenotype and function in the patient's body, on days 2, 7, 14, 21 and 28 after infusion, a sample of peripheral blood will be taken from patients to isolate PBMC. These PBMCs will be cultured in the presence of human IL-2 in a concentration of 200 U/mL. The cells will be incubated for 12 to 16 hours prior to the test. Intracellular IFN γ cytokine production and CD107 marker will be considered as an indicator for activation of the effector cells

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017083027520N9**
Registration date: **2017-10-19, 1396/07/27**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2017-10-19, 1396/07/27

Registrant information

Name

Mehdi Yousefi

Name of organization / entity

Department of Immunology, Faculty of Medicine,
Tabriz University of Medical Sciences, Tabriz, Iran

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Azarbayegan Stem Cell And Regenerative Medicine
Institute

Expected recruitment start date

2017-10-23, 1396/08/01

Expected recruitment end date

2018-04-21, 1397/02/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A Clinical trial to assess the effect of Natural Killer Cell

transplantation in treatment of patients with Acute lymphoblastic leukemia (ALL) and chronic lymphocytic leukemia (CLL)

Public title

Treatment of patients with leukemia using NK cells

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: 1-Age range of 18- 25 years for ALL patients; 2-Age range over 50 years for patients with CLL; 3- Those who have a proper cell donors with incongruent KIR (Haploidentical KIR-L mismatched donor); 4- Patients with adequate organ function; 5- Access to the patient for the continuation of treatment and follow-up (preferably from Azeri-speaking patients for easier access and removal of the Zentique variable); Exclusion criteria : 1-Patients with active and uncontrolled infections; 2-Abnormal kidney, lung and liver function, measured by serum creatinine (serum creatinine> 2 mg / dl), saturated oxygen O2 ≤ 96%) (Sat and liver enzymes (ALT / AST> 2.5 x N); 3-Patients with Down syndrome; 4- Patients with acute promyelocytic leukemia

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

1

Groups that have been masked

No information

Sample size

Target sample size: **10**

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Single

Other design features

In this study, we have one intervention group with 10 persons

Secondary Ids

1

Registry name

-

Secondary trial Id

-

Registration date

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Stem Cell And Regenerative Medicine Institute,Tabriz University of Medical Sciences

Street address

Stem Cell And Regenerative Medicine Institute, Shahid Madani Hospital, Golbad Ave, Tabriz

City

Tabriz

Postal code

Approval date

2017-08-28, 1396/06/06

Ethics committee reference number

IR.TBZMED.REC.1396.455

Health conditions studied

1

Description of health condition studied

Acute lymphoblastic leukemia (ALL)

ICD-10 code

C91.0

ICD-10 code description

Acute lymphoblastic leukaemia

2

Description of health condition studied

Chronic lymphocytic leukemia (CLL)

ICD-10 code

C91.1

ICD-10 code description

Chronic lymphocytic leukaemia

Primary outcomes

1

Description

Phenotype and function of NK cells

Timepoint

2, 7, 14, 21 and 28 days after the transplant

Method of measurement

Flow cytometry

Secondary outcomes

1

Description

IFN γ

Timepoint

2, 7, 14, 21 and 28 days after the transplant

Method of measurement

Flow cytometry

2

Description

CD107
Timepoint
2, 7, 14, 21 and 28 days after the transplant
Method of measurement
Flow cytometry

Intervention groups

1

Description

Injecting 29 * 106 /kg NK cells to patients with leukemia Intravenously and then Injection of Repetitive doses of IL-2 (6 doses) subcutaneously to stimulate the proliferation and activation of NK-positive cells in the patient's body.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Stem Cell And Regenerative Medicine Institute

Full name of responsible person

Mehdi Yousefi

Street address

Stem Cell And Regenerative Medicine Institute,
Madani Hospital, Golbad Ave, Tabriz

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Tabriz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Stem Cell And Regenerative Medicine Institute

Full name of responsible person

Mohammad Nouri

Street address

Stem Cell And Regenerative Medicine Institute,
Madani Hospital, Golbad Ave, Tabriz

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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

Stem Cell And Regenerative Medicine Institute

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Stem Cell And Regenerative Medicine Institute

Full name of responsible person

Leili Aghebati Maleki

Position

PhD of Medical Immunology

Other areas of specialty/work

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Person responsible for scientific inquiries

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Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

Sanam Dolati

Position

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Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty