

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Rituximab and Allogeneic Natural Killer Cells for Refractory Lymphoid Malignancies

Protocol summary

Registration timing: **prospective**

Study aim

This study aims to evaluate the safety and feasibility of intravenous systemic infusion of allogeneic NK cells in patients with relapsed or refractory lymphoma.

Last update: **2022-11-28, 1401/09/07**

Update count: **0**

Registration date

2022-11-28, 1401/09/07

Design

This is an open-label, non-randomized, interventional, single-group assignment study to assess the safety and feasibility of an allogeneic NK cell therapy derived from donor peripheral blood, in combination with rituximab, or other monoclonal antibodies, on ten patients with relapsed or refractory lymphoma.

Registrant information

Name

Leyla Sharifi Aliabadi

Name of organization / entity

Research Institute for Hematology, Oncology and Stem Cell Transplantation, Tehran University of Medic

Country

Iran (Islamic Republic of)

Phone

+98 21 8490 3691

Email address

ctu@sina.tums.ac.ir

Settings and conduct

The study is a single-group clinical trial to evaluate the safety of allogeneic in-vitro expanded Natural Killer Cells for relapsed refractory Lymphoid Malignancies at the Hematology-Oncology-Stem Cell Transplantation Research Center (HORCSCT) of Tehran University.

Participants/Inclusion and exclusion criteria

Adult patients with lymphoid malignancies and adequate organ function who failed to respond to at least two lines of treatment will be included in this study. Patients with brain lymphoma or HIV are excluded from the study.

Recruitment status

Recruitment complete

Funding source

Intervention groups

All patients will be assigned to the only interventional arm of the study. Patients in the interventional arm of the study will receive a single dose of systemic intravenous infusion of natural killer cells from an allogeneic donor.

Expected recruitment start date

2022-12-11, 1401/09/20

Expected recruitment end date

2023-08-23, 1402/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Main outcome variables

Natural Killer cell infusion-related Adverse Events, Acute Graft versus Host Disease

Scientific title

Rituximab and Allogeneic Natural Killer Cells for Refractory Lymphoid Malignancies

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20140818018842N26**

Registration date: **2022-11-28, 1401/09/07**

Public title

Cell therapy for Refractory Lymphoid Malignancies

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age 18 years or older adequate organ function at the time of infusion After the failure of at least 2 prior lines of therapy Histologically confirmed malignant lymphoma Adequate performance score: KPS >70 or ECOG 0-2

Exclusion criteria:

CNS lymphoma HIV patients Patients with a history of autoimmune disease

Age

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

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethics Committees of School of Medicine-
Tehran University of Medical Sciences

Street address

Kargar shomali Ave., Shariati hospital

City

Tehran

Province

Tehran

Postal code

1411713131

Approval date

2020-09-20, 1399/06/30

Ethics committee reference number

IR.TUMS.MEDICINE.REC.1399.500

Health conditions studied

1

Description of health condition studied

Hodgkin lymphoma

ICD-10 code

C81

ICD-10 code description

Hodgkin lymphoma

2

Description of health condition studied

Follicular lymphoma

ICD-10 code

C82

ICD-10 code description

Follicular lymphoma

3

Description of health condition studied

Non-follicular lymphoma

ICD-10 code

C83

ICD-10 code description

Non-follicular lymphoma

Primary outcomes

1

Description

Number of Patients With Grades 3-5 of Natural Killer cell
infusion-related Adverse Events

Timepoint

Daily during the first seven days after the injection and
then weekly until 28 days after the injection

Method of measurement

History, Physical exam, and lab test

2

Description

Number of Patients With Grades III-IV Acute Graft versus
Host Disease

Timepoint

Daily during the first seven days after the injection and
then weekly until 3 months after intervention

Method of measurement

History, Physical exam, and lab test

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: All patients are included in the only
intervention arm of the study. Patients in the
intervention arm will receive a dose of 10 million/kg

expanded NK cells on the day after the conditioning regimen. The injection of cells will be done within 30 minutes under full supervision and in an isolated room. The process of isolation and preparation of NK cells will be done in a clean room with clinical grade and suitable conditions for producing NK cells. From 21 days before the infusion, 20 to 30 cc of peripheral blood was taken from the third-party donor and after the isolation of mononuclear cells, CD56+/CD3- reproduced. A viability test is done using trypan blue and phenotyping is used to check the absolute number and purity of cells.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Hematology- Oncology and Stem Cell Transplantation Research Center, Tehran University of Medical Sci

Full name of responsible person

Maryam Barkhordar

Street address

North Kargar Ave.

City

Tehran

Province

Tehran

Postal code

1411713135

Phone

+98 21 8800 4140

Email

barkhordarm.n@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Mohamad Vaezi

Street address

North Kargar Ave.

City

Tehran

Province

Tehran

Postal code

1417713135

Phone

+98 21 8800 4140

Email

vaezi.mohammad@yahoo.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Tehran University of Medical Sciences

Proportion provided by this source

100

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

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Mohamad Ahmadvand

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Hematology

Street address

North Kargar Ave.

City

Tehran

Province

Tehran

Postal code

1411713135

Phone

+98 21 8800 4140

Email

ahmadvand.mohamad64@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Maryam Barkhordar

Position

Associate professor

Latest degree

Subspecialist

Other areas of specialty/work

Hematology

Street address

North Kargar Ave.

City

Tehran

Province

Tehran

Postal code

1411713135
Phone
+98 21 8800 4140
Email
barkhordarm.n@gmail.com

Person responsible for updating data

Contact

Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Mohamad Ahmadvand
Position
Tehran
Latest degree
Ph.D.
Other areas of specialty/work
Hematology
Street address
North Kargar Ave.
City
Tehran
Province
Tehran

Postal code
1411713135
Phone
+98 21 8800 4140
Email
madvand.mohamad64@yahoo.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

There is no further information

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available