Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Rituximab and Allogeneic Natural Killer Cells for Refractory Lymphoid Malignancies

Protocol summary

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.

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.

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.

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.

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

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20140818018842N26**
Registration date: **2022-11-28, 1401/09/07**
Registration timing: **prospective**

Last update: **2022-11-28, 1401/09/07**
Update count: **0**

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

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

Recruitment status
Recruitment complete

Funding source

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

Scientific title
Rituximab and Allogeneic Natural Killer Cells for Refractory Lymphoid Malignancies

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