Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Safety and efficacy of modified donor lymphocyte infusion (DLI) in reducing infection risk in adult patients with acute leukemia following allogeneic hematopoietic stem cell transplantation

Protocol summary

Study aim

Evaluation of safety and efficacy of modified donor lymphocyte infusion (DLI) in reducing infection risk in adult patients with acute leukemia following allogeneic hematopoietic stem cell transplantation

Design

clinical trial with control group, parallel groups, Un-randomized, open-labeled Sample size: 12, taking into account the loss: 15, Phase I and II

Settings and conduct

Patients with acute leukemia referred to Taleghani Hospital receive hematopoietic stem cell transplantation from a haplotype donor in the form of T cell replete with cyclophosphamide (Ptcy) and then modified DLI with time intervals of 4-6 weeks with increasing doses of 0.5 x 106, 106 x They receive 1 and 106 x 3 via peripheral vein catheter. Then clinical symptoms, laboratory tests for viral infections, laboratory tests for bacterial and fungal infections in case of clinical symptoms will perform rom the first dose of modified DLI infusion until one year after its last dose on days 90, 180, and 360.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Transplantation of T cell replete haplotype with cyclophosphamide/The estimated life expectancy more than one year/Karnofsky index above 70% Exclusion criteria: GVHD of grade 2 or less/Uncontrolled bacterial infection/Insufficient intake: WBC<2500/mm3 and Platelet<50000/mm3/Evidence of recurrence/Concomitant treatment with corticosteroids and/or other immunosuppressive drugs/Infection with hepatitis B, C and HIV pathogens

Intervention groups

Intervention group: Acute leukemia patients receive T cell repleted hematopoietic stem cell transplantation from a haplotype donor with cyclophosphamide (Ptcy) and then receive modified DLI. Control group: Acute leukemia patients only receive T cell repleted hematopoietic stem cell transplantation from a haplotype donor with cyclophosphamide (Ptcy).

Main outcome variables

Infection rate after treatment with modified DLI

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230801058996N4**
Registration date: **2024-06-19, 1403/03/30**
Registration timing: **prospective**

Last update: **2024-06-19, 1403/03/30**
Update count: **0**

Registration date

2024-06-19, 1403/03/30

Registrant information

Name

Elham Roshandel

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 5798 4000

Email address

elham.roshandel@sbmu.ac.ir

Recruitment status

recruiting

Funding source

Expected recruitment start date

2024-07-05, 1403/04/15

Expected recruitment end date

2027-07-06, 1406/04/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Safety and efficacy of modified donor lymphocyte infusion (DLI) in reducing infection risk in adult patients with acute leukemia following allogeneic hematopoietic stem cell transplantation

Public title

Reducing infection risk in adult patients with acute leukemia using modified donor lymphocyte infusion (DLI) following allogeneic hematopoietic stem cell transplantation

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Transplantation of T cell replete haplotype with cyclophosphamide The estimated life expectancy more than one year Karnofsky index above 70%

Exclusion criteria:

GVHD of grade 2 or less Uncontrolled bacterial infection Insufficient intake: WBC<2500/mm3 and Platelet<50000/mm3 Evidence of recurrence Concomitant treatment with corticosteroids and/or other immunosuppressive drugs Infection with hepatitis B, C and HIV pathogens

Age

From **20 years** old to **70 years** old

Gender

Both

Phase

1-2

Groups that have been masked

No information

Sample size

Target sample size: **12**

Randomization (investigator's opinion)

Not randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

کمیته اخلاق دانشگاه علوم پزشکی شهید بهشتی

Street address

Taleghani Hospital, Aarabi street, Yaman street, Chamran highway

City

Tehran

Province

Tehran

Postal code

۱۹۸۵۷۱۱۱۵۱

Approval date

2024-04-28, 1403/02/09

Ethics committee reference number

IR.SBMU.RETECH.REC.1403.039

Health conditions studied

1

Description of health condition studied

Acute leukemia

ICD-10 code

C95.0

ICD-10 code description

Acute leukemia of unspecified cell type

Primary outcomes

1

Description

Infection rate after treatment with modified DLI

Timepoint

From the first dose of modified DLI infusion until one year after its last dose on days 90, 180, and 360.

Method of measurement

Examining clinical symptoms, performing laboratory tests for viral infections, performing laboratory tests for bacterial and fungal infections in case of clinical symptoms.

Secondary outcomes

1

Description

Evaluation of "Overall survival" in a one year period.

Timepoint

From the first dose of modified DLI infusion until one year after its last dose

Method of measurement

Regular patient visits to bone marrow transplantation clinic for follow-up and regular telephone monitoring of patients.

Intervention groups

1

Description

Intervention group: Acute leukemia patients receive T cell repleted hematopoietic stem cell transplantation from a haplotype donor with cyclophosphamide (Ptcy) and then modified DLI with time intervals of 4-6 weeks with escalating doses of 0.5 x 106, 1 x 106 and 3 x 106 they receive.

Category

Treatment - Other

2

Description

Control group: Acute leukemia patients only receive T cell repleted hematopoietic stem cell transplantation from a haplotype donor with cyclophosphamide (Ptcy).

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Taleghani Hospital

Full name of responsible person

Elham Roshandel

Street address

Aarabi street, Yaman street, Chamran highway

City

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Phone

+98 21 2303 1658

Fax

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Email

info@sbmu.ac.ir

Web page address

https://taleghani.sbmu.ac.ir/

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Afshin Zarghi

Street address

Aarabi street, Daneshjou Boulevard, Velenjak

City

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1985717443

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Email

info@sbmu.ac.ir

Web page address

https://sbmu.ac.ir/

Grant name

Grant code / Reference number

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

No

Title of funding source

Javidan Motaher Charity Foundation of Tehran

Proportion provided by this source

50

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

2

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Afshin Zarghi

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Aarabi street, Daneshjou Boulevard, Velenjak

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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

Elham Roshandel

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Cell therapy

Street address

Aarabi street, Yaman street, Chamran highway

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Email

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Elham Roshandel

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Elham Roshandel

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Email

elham.roshandel@gmail.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

Due to the confidentiality of patient information

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

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

Clinical symptoms, Laboratory tests for viral infections, Laboratory tests for bacterial and fungal infections in case of clinical symptoms.

When the data will become available and for how long

Data files would be accessible after publication.

To whom data/document is available

Data files would be accessible to both academic researchers and industrial developers.

Under which criteria data/document could be used

Access to the data file will be provided for academic researchers to study. Data analysis is possible for use in meta-analysis review articles. Authentication of the applicant and provision of an academic email is required to access the data file.

From where data/document is obtainable

To receive the data file, please refer to the person in charge of the trial (Dr. Elham Roshandel): E-mail: elham.roshandel@gmail.com Phone number: 00982123031658 Address: Hematopoietic stem cell research center, Yas administrative complex, 4th floor, Taleghani Hospital, Aarabi street, Yaman street, Chamran highway, Tehran.

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

The applicant must state his/her request accurately and completely. The requested data will be provided within ten working days after receiving the request.

Comments