Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Feasibility, safety, effectiveness and toxicity of Post-transplant Expanded, Activated Haploidentical Natural Killer Cells Infusion in Haploidentical Hematopoietic Stem Cell Transplantation for Pediatric Patients with Acute Myeloid Leukemia: A Pilot Study

Protocol summary

Study aim

Infusion of expanded NK cells from healthy haploidentical donors to enhance anti -eukemia effect in pediatric patients with acute myeloid leukemia.

Design

A Pilot single arm clinical trial of 5 Patients

Settings and conduct

1. Haploidentical donors will donate 30 cc/kg (recipient body weight) of blood collected on day −30 for NK-cell production and will undergo peripheral blood apheresis on day 0 of transplant. 2. NK cells will be expanded and activated. 3. The purity of the product would be checked by flowcytometery using NK cell markers. 4. Assesment of activation of NK-cell product would be conducted via evaluation of cytokine secretion including IFN-γ. 5. Assesment of the product viability would be conducted via trypan blue dye exclusion. 6. Assesment of the functionality of the product would be done via cytotoxicity assay. 7. NK-cell product will be infused from cryopreserved aliquots on days +5 post transplant .

Participants/Inclusion and exclusion criteria

1. Age ≤ 18 years old. 2. Diagnosis of AML other than acute promyelocytic leukemia (APL) / candidate for first allogenic haploidentical HSCT. 3. Adequate organ function 4. Karnofsky or Lansky performance score of greater than or equal to 50. 5. At least two weeks since receipt of any systemic chemotherapy and/or radiation therapy.

Intervention groups

In this single arm study, Haploidentical activated expanded NK cell will be infused after Haploidentical HSCT in pediatric patients with AML.

Main outcome variables

1. To evaluate 1 year overall survival after infusion of expanded haploidentical NK cells. 2. To evaluate 1 year relapse-free survival after infusion of expanded haploidentical NK cells. 3. To evaluate 1 year relapse rate after infusion of expanded haploidentical NK cells.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20140818018842N33**
Registration date: **2023-04-03, 1402/01/14**
Registration timing: **registered_while_recruiting**

Last update: **2023-04-03, 1402/01/14**
Update count: **0**

Registration date

2023-04-03, 1402/01/14

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)

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+98 21 8490 3691

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-03-21, 1402/01/01

Expected recruitment end date

2025-03-21, 1404/01/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Feasibility, safety, effectiveness and toxicity of Post-transplant Expanded, Activated Haploidentical Natural Killer Cells Infusion in Haploidentical Hematopoietic Stem Cell Transplantation for Pediatric Patients with Acute Myeloid Leukemia: A Pilot Study

Public title
Feasibility, safety, effectiveness and toxicity of Post-transplant Expanded, Activated Haploidentical Natural Killer Cells Infusion in Haploidentical Hematopoietic Stem Cell Transplantation for Pediatric Patients with Acute Myeloid Leukemia: A Pilot Study

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Age ≤ 18 years old. Patients must have a diagnosis of AML other than acute promyelocytic leukemia (APL) according to WHO criteria and should be a candidate for their first allogenic haploidentical HSCT. All patients must have adequate organ function defined as:a. Renal Function: Age-adjusted serum creatinine ≤ to 1.5 x normal for age/gender OR creatinine clearance or GFR greater than or equal to 60 cc/min/1.73m2b. Liver Function: Total bilirubin ≤ 1.5 x normal for age, AND Alanine aminotransferase (ALT) is no more than 2 times the upper limit of normal and Aspartate transaminases (AST) is no more than 2 times the upper limit of normal.c. Cardiac Function: Normal ejection fraction documented by either echocardiogram or radionuclide MUGA evaluation OR Normal fractional shortening documented by echocardiogramd. Pulmonary Function: No dyspnea at rest, no oxygen requirement. Karnofsky or Lansky performance score of greater than or equal to 50. Potentially available haploidentical family donor (child/ sibling), willing and fit for NK cell donation At least two weeks since receipt of any biological therapy, systemic chemotherapy, and/or radiation therapy.

Exclusion criteria:
Pregnancy: Quantitative Serum B-HCG must be negative in girls who are post-menarchal Breast feeding women are not eligible. Active or uncontrolled infection Patient declines participation Second HSC

Age
To **18 years** old

Gender
Both

Phase
1-2

Groups that have been masked
No information

Sample size
Target sample size: **5**

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
Tehran University of Medical Sciences

Street address
North kargar st

City
Tehran

Province
Tehran

Postal code
146767

Approval date
2022-10-10, 1401/07/18

Ethics committee reference number
IR.TUMS.MEDICINE.REC.1401.540

Health conditions studied

1

Description of health condition studied
Acute Myeloid Leukemia

ICD-10 code
C92.0

ICD-10 code description
Acute myeloid leukemia

Primary outcomes

1

Description
Relapse free survival

Timepoint
1 year

Method of measurement
spss

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Pediatric Patients with Acute Myeloid Leukemia who are candidate to recieve Haploidentical Hematopoietic Stem Cell Transplantation 1. Haploidentical donors will donate 30 cc/kg (recipient body weight) of blood collected on day −30 for NK-cell production and will undergo peripheral blood apheresis on day 0 of transplant.2. NK cells will be expanded and activated.3. The purity of the product would be checked by flowcytometery using NK cell markers.4. Assesment of activation of NK-cell product would be conducted via evaluation of cytokine secretion including IFN-γ.5. Assesment of the product viability would be conducted via trypan blue dye exclusion.6. Assesment of the functionality of the product would be done via cytotoxicity assay.7. NK-cell product will be infused from cryopreserved aliquots on days +5 post transplant .

Category
Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center
Research Institute for Oncology, Hematology and Cell TherapyHematology

Full name of responsible person
Tahereh Rostami

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Tehran University of Medical Sciences

Full name of responsible person
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Web page address

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
Azadeh Kiumarsi

Position
Assistant professor

Latest degree
Subspecialist

Other areas of specialty/work
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Person responsible for updating data

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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
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available