

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Jul 2026

The safety and efficiency evaluation of allogenic Natural Killer cell therapy in relapsed Neuroblastoma pediatric patients post hematopoietic stem cell transplantation: Phase I clinical study

Protocol summary

Study aim

Launching a new cell therapy method for children with recurrent neuroblastoma after hematopoietic stem cell transplantation Evaluation of tolerability, complications, or immunity of NK cells in children with neuroblastoma for Disease-Free survival

Design

Open-label, one arm non-randomized trial of 5 patients

Settings and conduct

Administration of NK cells at a dose of 10 million per kilogram of body weight intravenously at the first time and if the dose is tolerated then administration of 50 million/kg three weeks later by a therapist at the Pediatric Cell Therapy Research Center.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Recurrent neuroblastoma after receiving hematopoietic stem cell transplant with the following criteria: 1) Any amount of neuroblastoma tumor cells in the bone marrow that can be seen from at least one aspiration sample 2) Tumors seen on CT in at least one soft tissue. 3) Have at least 1 MIBG-lesion with a score of 1-2 Curie 4) The patient has a life expectancy of at least 12 weeks. Lansky (under 16 years old) or Karnowski (over 16 years old) score 50. 5) The function of the patient organs must be acceptable. The hematologic function must be as follows: A. Absolute Phagocyte count (APC= neutrophils and monocytes): $\geq 1000/\mu\text{L}$ B. Absolute Neutrophil count: $\geq 750/\mu\text{L}$ C. Absolute Lymphocyte count $\geq 500/\mu\text{L}$ 6) Patient age from 1 to 15 years Exclusion criteria: Active or uncontrollable infection History of allergies or any sensitivity to animal proteins Heat failure Serious mental and physical disabilities Participation in any other clinical trial

Intervention groups

Administration of NK cells at doses of 10 and 50 million per kg of body weight without a control group

Main outcome variables

Tolerance, any complications or immunity of NK cells in children with neuroblastoma in terms of Disease-Free Survival

General information

Reason for update

Acronym

NKNB

IRCT registration information

IRCT registration number: **IRCT20201202049568N1**

Registration date: **2021-02-20, 1399/12/02**

Registration timing: **registered_while_recruiting**

Last update: **2021-02-20, 1399/12/02**

Update count: **0**

Registration date

2021-02-20, 1399/12/02

Registrant information

Name

Rashin Mohseni

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 6694 8444

Email address

rashin_mohseni@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-02-19, 1399/12/01

Expected recruitment end date

2022-02-20, 1400/12/01

Actual recruitment start date

empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The safety and efficiency evaluation of allogenic Natural Killer cell therapy in relapsed Neuroblastoma pediatric patients post hematopoietic stem cell transplantation: Phase I clinical study

Public title
Allogenic Natural Killer cell therapy in relapsed Neuroblastoma pediatric patients

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Any amount of neuroblastoma tumor cells in the bone marrow that can be seen from at least one aspiration sample Tumors seen on CT in at least one soft tissue. Have at least 1 MIBG- lesion with a score of 1-2 Curie The patient has a life expectancy of at least 12 weeks. The function of the patients organs must be acceptable. Patient age from 1 to 15 years
Exclusion criteria:
Active or uncontrollable infection History of allergies or any hypersensitivity to animal proteins Heart failure Serious mental and physical disabilities Participation in any other clinical trial

Age
From **1 year** old to **15 years** old

Gender
Both

Phase
1

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

Ethics committee of Tehran University of Medical Sciences

Street address

Pediatric Cell Therapy Research Center, Keshavarz Blvd, Dr Gharib St.

City

Tehran

Province

Tehran

Postal code

1419733151

Approval date

2020-11-21, 1399/09/01

Ethics committee reference number

IR.TUMS.MEDICINE.REC.1399.817

Health conditions studied

1

Description of health condition studied

Neuroblastoma

ICD-10 code

C74.90

ICD-10 code description

Malignant neoplasm of unspecified part of unspecified adrenal gland

Primary outcomes

1

Description

To measure tumor response after infusion of expanded activated NK cells. Response will be assessed as defined by Revised International Neuroblastoma Response Criteria 2017.

Timepoint

Each 6 month Over 2 years

Method of measurement

Disease status at primary and metastatic soft tissue sites will be assessed using MIBG scans or PET scan as applicable.

Secondary outcomes

1

Description

To measure the numbers of infused NK cells in peripheral blood at specific time-points after NK cell infusion

Timepoint

before intervention and 2, 4 , 6 month after intervention

Method of measurement

NK cells will be identified by flow cytometry in peripheral blood and their percentages and absolute numbers will be calculated.

Intervention groups

1

Description

Intervention group: NK cells that were isolated by CliniMACS from apheresis samples will be expanded over 10 days in a specific media with 10% serum and will be infused in combination with cyclophosphamide 60mg/kg on day -3 and day -2 prior to the NK cell infusion. NK cells will be injected intravenously at doses of 10 million and 50 million per kilogram of body weight at three-week intervals.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Pediatric Cell Therapy Research Center

Full name of responsible person

Amir Ali Hamidieh

Street address

Children's Medical Center Hospital, Gharib St.,
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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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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

Rashin Mohseni

Position

Consultant

Latest degree

Ph.D.

Other areas of specialty/work

Cell Therapy

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

Rashin Mohseni

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Cell Therapy and Regenerative Medicine

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

Not applicable

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

All collected deidentified IPD will be shared.

When the data will become available and for how long

January 2023

To whom data/document is available

academic institutions and hospitals

Under which criteria data/document could be used

No limitation

From where data/document is obtainable

Rashin Mohseni rashin_mohseni@yahoo.com

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

One year after the intervention

Comments