

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Jul 2026

Evaluating overall survival and the rate of GVHD in children and adolescents receiving antithymocyte globulin as an immunosuppressant during hematopoietic stem cell transplantation

Protocol summary

Study aim

Evaluating the overall survival and incidence of GVHD in children receiving T globulin 20 during hematopoietic stem cell transplant

Design

Open-label clinical trial with retrospective control group, on patients undergoing HSCT during a one year period

Settings and conduct

All patients undergoing HSCT during 1 year, at the Children's Medical Center will be enrolled in the study if they meet the eligibility criteria and will be prescribed anti-thymocyte globulin based on their protocol. The patients will be visited and assessed for acute and chronic GVHD and infections, daily during hospitalization, and after discharge: weekly until 3 months, biweekly until 6 months, then monthly until 12 months.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 1 to 18 year-old HSCT recipients
Providing written informed consent
Lansky score above 70%
Absence of severe active infection
Exclusion criteria: History of previous hematopoietic stem cell transplant
previous treatment with anti-thymocyte globulin in the last three months
abnormal liver, renal, and heart function

Intervention groups

Test group: anti-thymocyte globulin (manufactured by Kawsar Biotech Company) the dose and duration of administration will be based on the treatment protocol.
Control group: anti-thymocyte globulin (manufactured by Sanofi Genzyme) the dose and duration of administration was based on the treatment protocol, and this group has received the medication during the previous year.

Main outcome variables

Overall survival and GVHD

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210523051368N1**

Registration date: **2022-02-28, 1400/12/09**

Registration timing: **registered_while_recruiting**

Last update: **2022-02-28, 1400/12/09**

Update count: **0**

Registration date

2022-02-28, 1400/12/09

Registrant information

Name

maryam behfar

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 6147 2931

Email address

behfarm@sina.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-02-24, 1400/12/05

Expected recruitment end date

2023-02-24, 1401/12/05

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluating overall survival and the rate of GVHD in children and adolescents receiving antithymocyte globulin as an immunosuppressant during hematopoietic stem cell transplantation

Public title

Survival and incidence of GVHD in children receiving T globulin 25 as an immunosuppressant during hematopoietic stem cell transplantation

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

1 to 18 year-old hematopoietic stem cell transplant recipients with anti-thymocyte globulin in their conditioning regimen parents or legally acceptable representatives must have provided a written informed consent Lansky score above 70% Absence of severe active infection use of bone marrow or G-CSF-stimulated peripheral blood stem cells

Exclusion criteria:

History of previous stem cell transplantation (re-transplantation) use of umbilical cord blood stem cells history of previous treatment with anti-thymocyte globulin in the last three months Known allergic reaction to rabbit proteins abnormal liver function (total bilirubin greater than three times the upper limit of normal (ULN), conjugated bilirubin > 2 mg/dl, transaminases greater than three times the ULN) abnormal renal function adjusted for the patient's age abnormal heart function (left ventricular ejection fraction < 50% after ECHO, congestive heart failure, arrhythmia)

Age

From **1 year** old to **18 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **45**

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Other

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee in Research of Children's Medical Center-Tehran University of Medical Sciences

Street address

Childrens Medical Center, Gharib Ave, Keshavarz Blvd, Tehran

City

Tehran

Province

Tehran

Postal code

1419733151

Approval date

2021-10-19, 1400/07/27

Ethics committee reference number

IR.TUMS.CHMC.REC.1400.161

Health conditions studied

1

Description of health condition studied

hematopoietic stem cell transplantation

ICD-10 code

Z94.84

ICD-10 code description

Stem cells transplant status

2

Description of health condition studied

Graft Versus Host Disease

ICD-10 code

D89.810

ICD-10 code description

Acute graft-versus-host disease

3

Description of health condition studied

Graft Versus Host Disease

ICD-10 code

D89.811

ICD-10 code description

Chronic graft-versus-host disease

Primary outcomes

1

Description

Rate of acute GVHD

Timepoint

First 100 days after transplantation

Method of measurement

Physical examination and laboratory findings

2

Description

Overall survival
Timepoint
until 1 year after transplantation
Method of measurement
Mortality assessment

Secondary outcomes

1

Description
Rate of chronic GVHD
Timepoint
From 100 days until 1 year after transplantation
Method of measurement
Physical examination and laboratory findings

2

Description
Rate of bacterial infections
Timepoint
until 1 year after transplantation
Method of measurement
Blood culture

3

Description
Rate of fungal infections
Timepoint
until 1 year after transplantation
Method of measurement
Laboratory test (Aspergillus galactomannan antigen in blood by ELISA)

4

Description
Rate of viral infections
Timepoint
until 1 year after transplantation
Method of measurement
Laboratory test (RT-PCR for CMV infection)

5

Description
rejection
Timepoint
Until 1 month after transplantation
Method of measurement
evaluation of chimerism by Short tandem repeat or FISH

Intervention groups

1

Description
Intervention group: TGlobulin 25 (manufactured by Kawsar Biotech Company) with standard doses: haploidentical stem cell transplant, primary

immunodeficiency patients: 2.5 mg/kg from day -4 to -1, Aplastic anemia: 2.5 mg/kg from day -4 to -2, other related transplant: 2.5 mg/kg from day -2 to -1, one locus mismatched transplant: 2.5 mg/kg from day -3 to day -1, and unrelated donor transplant 2.5 mg/kg from day -3 to -1

Category

Treatment - Drugs

2

Description
Control group: antithymocyte globulin vials (manufactured by Sanofi Genzyme) with the same standard doses according to the type of transplantation, that had been administered through the previous year.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Children's Medical Center Hospital

Full name of responsible person

Maryam Behfar

Street address

Children's Medical Center Hospital, Gharib Ave, Keshavarz Blvd, Tehran

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behfarm@sina.tums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kowsar Biotechnology company

Full name of responsible person

Siroos Zeinali

Street address

N0 41, Majlesi st., Valiasr Street

City

Tehran

Province

Tehran

Postal code

1595645513

Phone

+98 21 8893 0143

Email

Kawsar_biotech@yahoo.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Kowsar Biotechnology company

Proportion provided by this source

100

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

Industry

Person responsible for general inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Maryam Behfar

Position

Associate professor

Latest degree

Subspecialist

Other areas of specialty/work

pediatric hematology and oncology

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

Amir Ali Hamidieh

Position

Professor

Latest degree

Subspecialist

Other areas of specialty/work

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Person responsible for updating data

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Name of organization / entity

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Position

Associate professor

Latest degree

Subspecialist

Other areas of specialty/work

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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

Undecided - It is not yet known if there will be a plan to
make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to

make this available