

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 2026

Effect of mesenchymal stem cells derived from the placenta and their secretome for the treatment of GVHD: A triple-blinded randomized clinical trial

Protocol summary

Study aim

Determining the safety, feasibility and effectiveness of secretome derived from mesenchymal stem cells for GVHD patients

Design

This study will have a control group in parallel with the simple randomization method. The type of study will be triple-blinded in phase 3 on 30 patients.

Settings and conduct

In this clinical trial study, 30 patients with GVHD, who were referred to Shahid Qazi Hospital in Tabriz, were randomly divided into 2 groups of 15 people, and the intervention and control groups received secretome and distilled water by injection, respectively. The method of blinding will be triple-blinded and all the names and personal information of the patients will be coded at the time of data collection and will remain completely confidential.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 1- Patients with acute GVHD with fever requiring hospitalization Exclusion criteria: 1- Having sepsis

Intervention groups

1- Secretome recipient group 2- Control group receiving distilled water

Main outcome variables

Skin rash, liver involvement, intestine condition

General information

Reason for update

Acronym

GVHD

IRCT registration information

IRCT registration number: **IRCT20201108049311N7**

Registration date: **2023-09-28, 1402/07/06**

Registration timing: **registered_while_recruiting**

Last update: **2023-09-28, 1402/07/06**

Update count: **0**

Registration date

2023-09-28, 1402/07/06

Registrant information

Name

Seyyede Mina Hejazian

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 41 3336 9331

Email address

smhjl.biotech@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-08-23, 1402/06/01

Expected recruitment end date

2024-03-02, 1402/12/12

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of mesenchymal stem cells derived from the placenta and their secretome for the treatment of GVHD: A triple-blinded randomized clinical trial

Public title

Mesenchymal stem cells derived from the placenta and its secretions in the treatment of graft versus host disease

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with acute GVHD with fever and requiring hospitalization

Exclusion criteria:

Patients with sepsis

Age

From **16 years** old to **50 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Outcome assessor
- Data analyser

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

Thirty men and women with GVHD will be randomly assigned into two groups receiving intravenous secretome (15 people) or distilled water (15 people) using the random block method using blocks 4 and 6 through RAS (Random Allocation Software) and allocation ratio 1:1. In order to conceal the allocation, the secretome and distilled water will be placed in opaque vials numbered from 1 to 30. Participants will receive vials numbered 1 to 30 based on the order of entering the study. Preparing the vials and numbering them will be done based on the generated random sequence by a person not involved in the research.

Blinding (investigator's opinion)

Triple blinded

Blinding description

This study will be a triple-blinded study. In this way, the doctor will introduce the patients to receive secretome/distilled water and will not be aware of the grouping. Participating volunteers will not know about receiving secretome, distilled water, or other drugs. Secretome and distilled water will be placed in similar and coded vials. In addition, the placebo (distilled water) will be identical in appearance (shape and color), taste, and smell with secretome. In addition, due to the coding of patients and the lack of clarity in the grouping of patients, the data analyzer will be also blinded.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Tabriz University of Medical Sciences

Street address

Tabriz University of Medical Sciences, Golgasht street, Tabriz

City

Tabriz

Province

East Azarbaijan

Postal code

5166614766

Approval date

2023-05-08, 1402/02/18

Ethics committee reference number

IR.TBZMED.REC.1402.132

Health conditions studied

1

Description of health condition studied

Graft versus host disease

ICD-10 code

D89.81

ICD-10 code description

Graft-versus-host disease

Primary outcomes

1

Description

Skin rash

Timepoint

At the beginning of the study and 6 weeks after the intervention

Method of measurement

Examination of appearance (shape, color and texture of skin rash), determination of BSA percentage and staging based on it

2

Description

Liver involvement

Timepoint

At the beginning of the study and 6 weeks after the intervention

Method of measurement

Measurement of Bilirubin level

3

Description

Intestine condition

Timepoint

At the beginning of the study and 6 weeks after the intervention

Method of measurement
Diarrhea volume measurement

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Recipient of 6 doses secretome (set of substances released from the cell to its surroundings) of mesenchymal stem cells retrieved from the placenta (containing 400 microgram protein/ milliliter) (It will be produced through the cell culture from the placenta in the laboratory) 4 cc dissolved in albumin 20% every week for 6 weeks

Category

Treatment - Drugs

2

Description

Control group: Recipient of 6 doses of 4 cc distilled water dissolved in albumin 20% every week for 6 weeks

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Ghazi Hospital of Tabriz

Full name of responsible person

Dr. Hussein Ghasemi Moghaddam

Street address

Daneshgah St., Shahid Ghazi Hospital

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Dr. Parviz Shahabi

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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

Tabriz 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

Tabriz University of Medical Sciences

Full name of responsible person

Dr. Abolfazl Barzegari

Position

Non-faculty researcher

Latest degree

Ph.D.

Other areas of specialty/work

Medical Biotechnology

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Stem Cell And Regenerative Medicine Institute, Tabriz
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Person responsible for scientific

inquiries

Contact

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Dr. Hussein Ghasemi Moghaddam

Position

Subspecialty physician

Latest degree

Subspecialist

Other areas of specialty/work

Hematology

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Hematology and Oncology Research Center, Shahid
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Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

Dr. Hussein Ghasemi Moghaddam

Position

Subspecialty physician

Latest degree

Subspecialist

Other areas of specialty/work

Hematology

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Email

dr.ghasemi621@gmail.com

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

Not applicable

Data Dictionary

Not applicable