

Clinical Trial Protocol

Iranian Registry of Clinical Trials

24 Jul 2026

Investigating the effectiveness of using platelet gel obtained from allogeneic umbilical cord blood in the treatment of foot ulcers in patients with diabetes: a phase 2 randomized clinical trial

Protocol summary

Study aim

Investigating the effectiveness of using platelet gel obtained from allogeneic umbilical cord blood in the treatment of diabetic foot ulcers

Design

A clinical trial with a control group, with parallel groups, double-blind, NO randomized, phase 2 on 20 patients.

Settings and conduct

The time frame of the study will be from November 1401 to one year after that. The selection of patients will be based on the diabetic foot ulcer criteria, which will be done with the help of an endocrinologist. The surface of the wound should be more than 2 cm² and less than 5 cm². It is one of the main criteria for choosing a wound. It is tried to be the same for the control and intervention parts in each patient as much as possible. Intervention with platelet gel and smaller wound is considered as a control. Comparison of wounds before and after treatment is done for each patient with another part of his wound (two wounds from one patient). Umbilical cord blood is supplied from the cord blood bank of the maternity department of Erfan Niayesh Hospital, and all quality control tests are performed by the same center. Platelet gel processing and administration to patients will be done in a clean room. The patient is invited after obtaining the code of ethics from the ethics committee of Shahid Beheshti University of Medical Sciences, and the period of patient admission will last up to 6 months. By selecting 20 patients in this period, treatment intervention will begin.

Participants/Inclusion and exclusion criteria

If more than one year has passed since the wound was created, the wound must be in the leg area

Intervention groups

In two sections, intervention and control

Main outcome variables

Reducing the surface and depth of the wound

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210422051040N1**

Registration date: **2023-03-30, 1402/01/10**

Registration timing: **registered_while_recruiting**

Last update: **2023-03-30, 1402/01/10**

Update count: **0**

Registration date

2023-03-30, 1402/01/10

Registrant information

Name

Hojjat allah Abbaszadeh

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 4487 2764

Email address

dr.abbaszadeh@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-03-11, 1401/12/20

Expected recruitment end date

2023-04-21, 1402/02/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the effectiveness of using platelet gel obtained from allogeneic umbilical cord blood in the treatment of foot ulcers in patients with diabetes: a phase 2 randomized clinical trial

Public title

Investigating the effectiveness of using platelet gel obtained from allogeneic umbilical cord blood in the treatment of foot ulcers in patients with diabetes

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

The presence of diabetic foot ulcer criteria
Ulcers in the leg tissue
The wound area is more than 2 cm² and less than 5 cm²
The patient does not have HIV, HBV, HCV, HTLV1 viral infections
The patient does not have an acute bacterial infection
Patient age from 40 to 70 years.
Adherence to medication regimen by diabetic patients
HbA1C in the normal range (HbA1C<6.5)

Exclusion criteria:

Abuse of drugs and alcohol smoking
Severe vascular diseases, lupus, rheumatoid arthritis, kidney failure
Acute bacterial infection and sepsis
Cancer and use of cytotoxic drugs

Age

From **40 years** old to **70 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **20**

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

Ethics Committee at Shahid Beheshti Medical University in Tehran, Iran

Street address

Shahid Beheshti Medical University in Tehran

City

tehran

Province

Tehran

Postal code

1985717443

Approval date

2023-03-06, 1401/12/15

Ethics committee reference number

IR.SBMU.LASER.REC.1401.003

Health conditions studied

1

Description of health condition studied

Diabetes and healing

ICD-10 code

E08

ICD-10 code description

Diabetes mellitus due to underlying condition

Primary outcomes

1

Description

Diabetic wound healing rate

Timepoint

Measure the recovery rate after 2 weeks, 1 month and 3 months

Method of measurement

Measuring the surface and depth of the wound

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: PLATELET GEL. Separation of platelet-rich plasma and centrifugation according to the protocol (15 minutes at 2450 g for platelet concentration). In the next step, to prepare the platelet gel, the enriched plasma is mixed with thrombin and calcium gluconate inside the blood bag of the sterile child and it can be used after half an hour. . The gels will be used locally in the wound without debridement of the intervention site. This operation will be done every other day for three days.

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center
SHOHADA TAJRISH HOSPITAL
Full name of responsible person
REZA ROBATI
Street address
TAJRISH SQUIRE
City
TEHRAN
Province
Tehran
Postal code
19899 34148
Phone
+98 21 25719
Email
INFO@SBMU.AC.IR

Full name of responsible person
RASHIN MOHSENI
Position
Assistant professor
Latest degree
Ph.D.
Other areas of specialty/work
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Province
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1417653761
Phone
۸۱۶۳۱۰
Email
rashin_mohseni@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
AFSHIN ZARGHI
Street address
VELENJAK
City
TEHRAN
Province
Tehran
Postal code
19395-4719
Phone
+98 21 23871
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INFO@SBMU.AC.IR

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Shahid Beheshti 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

Person responsible for scientific inquiries

Contact

Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
hojjat allah abbaszadeh
Position
Associate professor
Latest degree
Ph.D.
Other areas of specialty/work
Anatomy
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dr.abbaszadeh79@gmail.com

Person responsible for updating data

Contact

Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
hojjat allah abbaszadeh
Position
Associate professor
Latest degree
Ph.D.
Other areas of specialty/work
Anatomy
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19395-4719

Phone

+98 21 23872

Email

dr.abbaszadeh79@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is 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

No - There is not a plan to make this available

Clinical Study Report

Yes - There is 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

Title and more details about the data/document

Only a part of the data, such as the information related to the main result or the like, can be shared.

When the data will become available and for how long

The access period starts 6 months after the results are published

To whom data/document is available

For researchers working in academic and scientific institutions

Under which criteria data/document could be used

It can be used with the written permission of the owner of the idea

From where data/document is obtainable

by Email

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

Written permission from the person in charge and the owner of the work

Comments