Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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 SQURE
City
TEHRAN
Province
Tehran
Postal code
19899 34148
Phone
+98 21 25719
Email
INFO@SBMU.AC.IR

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
Email
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
Full name of responsible person
RASHIN MOHSENI
Position
Assistant professor
Latest degree
Ph.D.
Other areas of specialty/work
cellular sciencese
Street address
enghlab squre
City
تهران
Province
Tehran
Postal code
1417653761
Phone
۸۱۶۳۱۰
Email
rashin_mohseni@yahoo.com

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
Street address
velenjak
City
Tehran
Province
Tehran
Postal code
19395-4719
Phone
+98 21 23872
Email
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
Street address

velenjak
City
Tehran
Province
Tehran
Postal code
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