

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Evaluation of the efficacy of platelet-rich plasma in non-infectious diabetic wound healing

Protocol summary

Study aim

Comparison of clinical outcome and amputation rate in non-infective diabetic wounds treated with platelet-rich plasma and conventional methods

Design

Two arm parallel groups randomised trial with blinded postoperative care and outcome assessment

Settings and conduct

The implementation of the randomization process will be done through the design of random blocks. PRP injection is performed twice a week for three weeks and questionnaires for both groups will be filled after wound healing or deciding to amputate or transform treatment plan.

Participants/Inclusion and exclusion criteria

Inclusion criteria are diabetic patients with grade 1 and 2 lower extremity ulcers and exclusion criteria are patients' unwillingness to continue treatment.

Intervention groups

Taking 20 cc of blood twice a week and injecting PRP twice a week and routine foot dressing

Main outcome variables

Duration of recovery; Amputation rate; Amputation level

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20160803029181N8**

Registration date: **2019-11-23, 1398/09/02**

Registration timing: **registered_while_recruiting**

Last update: **2019-11-23, 1398/09/02**

Update count: **0**

Registration date

2019-11-23, 1398/09/02

Registrant information

Name

Nasser Malekpour Alamdari

Name of organization / entity

Shahd Behesht University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 2207 4089

Email address

nassermalekpour@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-09-23, 1398/07/01

Expected recruitment end date

2020-01-21, 1398/11/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the efficacy of platelet-rich plasma in non-infectious diabetic wound healing

Public title

Evaluation of the efficacy of platelet-rich plasma in non-infectious diabetic wound healing

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Diabetic patients with grade 1 and 2 lower extremity ulcers

Exclusion criteria:

The patient's unwillingness to continue treatment

Increased wound grade

Age
No age limit

Gender
Both

Phase
N/A

Groups that have been masked

- Participant
- Care provider
- Data analyser
- Data and Safety Monitoring Board

Sample size
Target sample size: **90**

Randomization (investigator's opinion)
Not randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description
The form of dressing was the same in both groups, and the clinical care and data analysts did not know what dressing was used.

Placebo
Not used

Assignment
Parallel

Other design features
Production of autologous enriched platelet plasma

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Commity of Shahid Beheshti University of Medical Sciences

Street address

Shahid Beheshti University of Medical Sciences, Danshju blvd., Velenjak

City

Tehran

Province

Tehran

Postal code

1985717443

Approval date

2018-04-21, 1397/02/01

Ethics committee reference number

IR.SBMU.RETECH.REC.1396.547

Health conditions studied

1

Description of health condition studied

Diabetic foot ulcer

ICD-10 code

Z86.31

ICD-10 code description

Personal history of diabetic foot ulcer

Primary outcomes

1

Description

Healing time

Timepoint

At the beginning of the study and when 90% recovery is achieved

Method of measurement

Wound size with meter

Secondary outcomes

1

Description

Amputation

Timepoint

At baseline, 4 weeks later, and 8 weeks later

Method of measurement

Clinical observation

Intervention groups

1

Description

Intervention group: Dressing with platelet-rich 2C plasma every 3 days until 90% wound healing

Category

Treatment - Other

2

Description

Control group: Normal dressing with silversulfadiazine daily up to 90% wound healing

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Modarres hospital

Full name of responsible person

Nasser Malekpour

Street address

Modarres Hospital; Kaj Sq; Saadat abad

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Tehran
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nassermalekpour@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Seyyed Ali Ziai
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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

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
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Nasser Malekpour Alamdari
Position
Associate professor
Latest degree
Subspecialist
Other areas of specialty/work

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

No more information

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available