Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Jul 2026

The use of human stromal vascular fraction(SVF) and platelet-rich plasma(PRP) in treatment of therapy-resistant diabetic foot ulcers: a randomized control trial phase III

Protocol summary

Study aim
The effects of PRP and SVF on the healing of diabetic foot ulcers in patients resistant to conventional treatments

Design
A clinical trial with the control group, with parallel groups, randomized, phase 3 on 20 patients. A table of random numbers is used with online software.

Settings and conduct
Twenty patients with treatment-resistant diabetic foot ulcers on the Wagner scale referred to Mashhad Velayat Hospital were included and after obtaining informed consent, they were divided into 4 groups. The healing rate of diabetic foot ulcers is evaluated for 6 months. Also, oxidative stress, angiogenesis, and inflammation factors are measured in serum. The miRNA levels in the peripheral blood serum will be done.

Participants/Inclusion and exclusion criteria
Inclusion criteria: 1- Diabetic ulcer grade 1 to 4 2- A single wound in the legs and extremities that has been at least 4 weeks old 3- No smoking, alcohol and drugs 4- Not taking drugs that interfere with wound healing 5- Not having a simultaneous disease 6- Informed consent Exclusion criteria: 1. osteomyelitis 2. Visibility of bone in the area of treatment 3. Infectious diabetic foot ulcer 4. Charcot deformity 5. History of chemotherapy or radiation therapy in the past 3 months 6. Hemoglobin less than 10mg/dL 7. History of treatment with growth factors during the last two weeks 8. Platelets less than 100,000 per cc of plasma 9. Vascular problems should not be observed in the wound

Intervention groups
Four groups of 5 each: 1- The diabetic wound is treated with PRP twice a week for one month 2- 100 ml of the adipose tissue is collected in an autologous from the patient 3- PRP+SVF treatment 4- As the control group, the common treatment includes a combined treatment surgery, infection control,..

Main outcome variables
The size and depth of the wound; Stress oxidative; Inflammatory and Angiogenesis factors

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20130811014330N9**
Registration date: **2023-09-25, 1402/07/03**
Registration timing: **registered_while_recruiting**

Last update: **2023-09-25, 1402/07/03**
Update count: **0**

Registration date
2023-09-25, 1402/07/03

Registrant information

Name
Hamid Reza Rahimi

Name of organization / entity
Mashhad University of Medical Sciences

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-08-23, 1402/06/01

Expected recruitment end date
2025-08-23, 1404/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The use of human stromal vascular fraction(SVF) and platelet-rich plasma(PRP) in treatment of therapy-resistant diabetic foot ulcers: a randomized control trial phase III

Public title

Human stromal vascular fraction(SVF) and platelet-rich plasma(PRP) in treatment of therapy-resistant diabetic foot ulcers

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Having a diabetic ulcer grade 1 to 4 according to Wagner's classification Having a single wound in the legs and extremities (fingers, soles, heels, on the toes) that has been at least 4 weeks old No smoking, alcohol and drug addiction Not taking drugs that may interfere with wound healing, such as corticosteroids, immunosuppressive agents, and cytotoxic agents Not having concurrent diseases such as cancers, vasculitis, kidney and liver failure, and heart failure that may cause problems in wound healing Informed consent of patients

Exclusion criteria:

Patients with acute bone inflammation or osteomyelitis A wound with visible bone in the target area of treatment Infected diabetic foot ulcers Charcot deformity History of treatment with chemotherapy drugs or radiation therapy in 3 months before the start of treatment Hemoglobin less than 10mg/dL History of treatment with growth factors during two weeks before starting treatment Patients with less than 100,000 platelets Vascular problems should not be observed in the wound (not ABI˂0.7)

Age

No age limit

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **20**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization method: block Build random sequences: Randomization website (Randomaize.com) Allocation Concealment: SNOSE (sequentially numbered, opaque, sealed envelopes) According to the two intervention and control groups, the number of each block will be five. Then, write a list of blocks and assign numbers to them, which will be four blocks according to the sample size of 20 people. After that, random numbers between one and four are selected according to the randomization website (Randomaize.com). Finally, the allocated treatment list is written based on random numbers on the envelopes.

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 of Mashhad University of Medical Sciences

Street address

Quraishi bilding of MUMS, Daneshgah St., Mashhad, Iran

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Approval date

2023-07-01, 1402/04/10

Ethics committee reference number

IR.MUMS.REC.1402.105

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

The size of the wound

Timepoint

before dressing and after dressing in the first, second, third, and fourth week after treatment and then in the second, fourth, and sixth months after intervention

Method of measurement

Digital photographic camera, sterile metal ruler

2

Description
Wound depth
Timepoint
before dressing and after dressing in the first, second, third, and fourth week after treatment and then in the second, fourth, and sixth months after intervention
Method of measurement
Sterile metal measuring cup

Secondary outcomes

1

Description
Stress oxidative markers
Timepoint
6 Months after intervention
Method of measurement
Gene expression level by Real time PCR

2

Description
Angiogenesis and inflammation markers
Timepoint
6 Months after intervention
Method of measurement
Gene expression level by Real time PCR

3

Description
miRNA levels in serum of peripheral blood
Timepoint
6 Months after intervention
Method of measurement
Gene expression level by Real time PCR

Intervention groups

1

Description
Control group: As the control group, the common treatment for the patient is considered. The common treatment for these patients is a combined treatment including surgery, infection control, etc., which is prescribed to the patient at the discretion of the treatment staff and depending on the type and severity of the wound.
Category
Other

2

Description
Intervention group: In this group, the diabetic wound is treated with PRP twice a week for one month. In this way, in each session, 50 ml of blood is taken from the patient in a tube containing citrate phosphate dextrose or sodium citrate anticoagulant. PRP is prepared from the patient's plasma according to the protocol. The necrotic part of the wound is surgically removed by the attending physician and after washing the wound three times with hydrogen peroxide and normal saline, the wound is photographed. Then, depending on the area of the wound, up to 5 ml (per session) of PRP solution prepared by the surgeon is injected. It should be noted that the injection is done at several points of the edges of the wound so that the environment of the edge of the wound is properly covered. After that, the wound is bandaged with a wet silicone bandage.
Category
Treatment - Other

3

Description
Intervention group: About 100 ml of the patient's fat tissue is collected by the negative-pressure liposuction technique in an autologous manner from the patient himself through surgery. Then, the fat tissue taken in sterile conditions under the laminar hood is transformed into smaller pieces with a surgical blade, and the amount of blood remaining in it will be removed after washing twice with normal saline. The total volume of SVF solution is 60 cc, and it contains 30 x 106 live cells for one injection in the study. The injection method is that 20 cc of SVF solution containing 10 x 106 live cells will be injected into the subcutaneous tissues around the wound (with low injection volumes, 0.5 cc). Another 20 cc of SVF solution containing 10 x 106 live cells will be injected into the wound bed (with low injection volumes, 0.5 cc). 10 cc of SVF solution containing 5 x 106 viable cells will be injected at the level of the ankle, parallel to the anterior tibial artery, and pedis dorsalis (with low injection volumes, 0.5 cc). 10 cc of SVF containing 5 x 106 viable cells will be injected at the level of the ankle, parallel to the posterior tibial artery (with low injection volumes, 0.5 cc). The injection will be done after removing the necrotic part of the wound by surgery and after washing the wound three times with hydrogen peroxide and normal saline, the wound will be photographed and then the injection will be done according to the described method.
Category
Treatment - Other

4

Description
Intervention group: PRP+SVF treatment is used in this group. For this reason, SVF is separated like the second group. The volume of 30 cc of SVF contains 15 x 106 live cells for one injection. The injection method is that 10 cc of SVF containing 5 x 106 live cells will be injected into the subcutaneous tissues around the wound (with low injection volumes, 0.5 cc). 10 cc of SVF containing 5 x 106 viable cells will be injected into the wound bed (with low injection volumes, 0.5 cc). 5 cc of SVF containing 2.5 x 106 viable cells will be injected at the level of the ankle, parallel to the anterior tibial artery, and pedis dorsalis (with low injection volumes, 0.5 cc). 5 cc of SVF containing 2.5 x 106 viable cells will be injected at the

level of the ankle, parallel to the posterior tibial artery (with low injection volumes, 0.5 cc). In this group, for the treatment with PRP, about 50 ml of autologous blood is taken from the patient and PRP is prepared like the RPR preparation protocol in the first group. In this group, the injection will be once a week for a month. Depending on the area of the wound, up to 5 ml (per session) of PRP solution prepared by the surgeon is injected. It should be noted that the injection is done at several points of the edges of the wound so that the environment of the edge of the wound is properly covered. After that, the wound is bandaged with a wet silicone bandage. Wet silicone dressing is changed every three days.

Category
Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center
Velayat Hospital
Full name of responsible person
Hamid Reza Rahimi
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No 10, intersection of Shahid Kaveh and Namaz, Shahid Kaveh Boulevard,
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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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
Mashhad 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
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Full name of responsible person
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Position
Assistant Professor
Latest degree
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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Not applicable

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Not applicable

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

Clinical documentation is published with confidentialy

When the data will become available and for how long

One year after the end of sampling

To whom data/document is available

Available for people working in academic institutions

Under which criteria data/document could be used

For further research

From where data/document is obtainable

Dr. Hamid Reza Rahimi

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

Approved by the Research Committee of Mashhad Medical University

Comments