Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Investigate The effectiveness of platelet cryogen in improving diabetic foot ulcers compared to routine wound treatment methods.

Protocol summary

Study aim
Determining the effect of platelet cryogel on the healing of diabetic foot ulcers

Design
Clinical trial with intervention and control group, double blind, randomized, on 46 patients

Settings and conduct
Context: Clinical Location: Shahrekord Ayatollah Kashani Hospital Methods: 46 diabetic patients with similar diabetic foot ulcers are selected. The number of studied groups is 2 groups of 23, and the control group receives only routine treatment. In addition to the routine treatment, the second group uses 50 grams of platelet cryogel every three days. Double-blind: a list of groups A, B, which represents the intervention and control groups, coding and random selection of subjects without informing the researcher and the patients about the type of treatment received (in both groups) double-blindness of the study to be observed

Participants/Inclusion and exclusion criteria
Inclusion criteria: 1. Willingness to cooperate with the plan 2. Diabetic patients with fasting blood sugar higher than 126 mg/dL and two-hour blood sugar higher than 200 mg/dL 3. Age 40 to 70 years old with chronic foot ulcer without other accompanying diseases and by gender Exit criteria: 1. The patient's lack of consent to continue cooperation 2. Death of the patient 3. The patient being treated with other chronic wound treatment methods 4. Getting other diseases

Intervention groups
The number of studied groups is 2 groups of 23, and the control group receives only routine treatment. In addition to the routine treatment, the second group uses 50 grams of platelet cryogel every three days.

Main outcome variables
Level of Education Age sex alcohol consumption Duration of diabetes BMI, FBS, Hb A1C, wound area, smoking, blood pressure, insulin use, antidiabetic use, previous wound treatment

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20221206056726N1**
Registration date: **2023-02-07, 1401/11/18**
Registration timing: **retrospective**

Last update: **2023-02-07, 1401/11/18**
Update count: **0**

Registration date
2023-02-07, 1401/11/18

Registrant information

Name
Masoud Fatehi

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 83 3331 4112

Email address
fatehi67@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-03-21, 1398/01/01

Expected recruitment end date
2021-03-18, 1399/12/28

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title

Investigate The effectiveness of platelet cryogen in improving diabetic foot ulcers compared to routine wound treatment methods.

Public title

Investigate The effectiveness of platelet cryogel in improving diabetic foot ulcers compared to routine wound treatment methods

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Willing to cooperate with the project Diabetic patients with fasting blood sugar higher than 126 mg/dL and two-hour blood sugar higher than 200 mg/dL Age 40 to 70 years old with chronic foot ulcer without other comorbidities and separated by sex

Exclusion criteria:

The patient's lack of consent to continue cooperation Death of the patient The patient being treated with other chronic wound treatment methods. Getting other diseases

Age

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

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **46**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, diabetic patients with grade 2 or 3 chronic foot ulcers and contaminated type referring to Kashani Shahrekord Hospital were eligible and based on the information contained in the file, after explaining the goals and details of the individual's plan and desire, they were invited to participate in this research. If the answer is positive, first the consent form for participating in the study was obtained. The final stage of selecting people to enter the study was done based on the criteria for entering and not entering the study. Then the eligible people were randomly divided into two groups. Before the start of the study, a list of groups A, B, which represents the intervention and control groups, was coded, and the subjects were randomly selected by themselves without informing the researcher and the patients about the type of treatment received (in both groups) in a double-blind manner. Being a study should be considered.

Blinding (investigator's opinion)

Double blinded

Blinding description

In this study, diabetic patients with grade 2 or 3 chronic foot ulcers and contaminated type referring to Kashani Shahrekord Hospital were eligible and based on the information contained in the file, after explaining the goals and details of the individual's plan and desire, they were invited to participate in this research. If the answer is positive, first the consent form for participating in the study was obtained. The final stage of selecting people to enter the study was done based on the criteria for entering and not entering the study. Then the eligible people were randomly divided into two groups. Before the start of the study, a list of groups A, B, which represents the intervention and control groups, was coded, and the subjects were randomly selected by themselves without informing the researcher and the patients about the type of treatment received (in both groups) in a double-blind manner. Being a study should be considered.

Placebo

Not used

Assignment

Other

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of sharekord University of Medical Sciences

Street address

Social Research Center, School of Nursing and Midwifery, University of Medical Sciences, Rahmatiya, Shahr e Kord

City

sharekord

Province

Chahar-Mahal-va-Bakhtiari

Postal code

8813833435

Approval date

2020-02-23, 1398/12/04

Ethics committee reference number

IR.SKUMS.REC.1398.245

Health conditions studied

1

Description of health condition studied

Diabetic foot ulcer

ICD-10 code

E08.621

ICD-10 code description

Diabetes mellitus due to underlying condition with foot ulcer

Primary outcomes

1

Description
Chronic foot ulcer grade 2 or 3 and contaminated type
Timepoint
1 first day, 2 fifth day, 3 ninth day and 4 fourteenth day
Method of measurement
Sterile ruler

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: In addition to the routine treatment, the intervention group uses 50 grams of platelet cryogel once every three days.
Category
Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Shahrekord Kashani Hospital
Full name of responsible person
Massoud Fatehi
Street address
School of Nursing and Midwifery, Shahrekord Medical University, Rahmatiya, Shahr e Kord,
City
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MASOUD.FATEHI67@GMAIL.COM

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahre-kord University of Medical Sciences
Full name of responsible person
Elham Raisi
Street address
Social Research Center, School of Nursing and Midwifery, University of Medical Sciences, Rahmatiya, Shahr e Kord
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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
Shahre-kord 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
Shahre-kord University of Medical Sciences
Full name of responsible person
Masoud Fatehi
Position
Assistant Professor
Latest degree
Specialist
Other areas of specialty/work
General Surgery
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Person responsible for scientific inquiries

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Full name of responsible person

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Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

General Surgery

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Person responsible for updating data

Contact

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Full name of responsible person

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Position

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Latest degree

Specialist

Other areas of specialty/work

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Email

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

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

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is 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

Title and more details about the data/document

Only part of the data, such as information related to the main outcome or similar, can be shared.

When the data will become available and for how long

2021/03/18

To whom data/document is available

Researchers

Under which criteria data/document could be used

They can use for reference.

From where data/document is obtainable

Masoud Fatehi

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

Communicating with Mr. Masoud Fatehi through his email to receive information and guidance.

Comments