Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Comparing the effect of Prolotherapy with Placebo, in patients with diabetic foot ulcer

Protocol summary

Study aim
Determining the effect of local dextrose injection on pain, wound healing process and inflammatory markers in patients with diabetic foot ulcer

Design
Two arm parallel group block randomised trial with triple-blinded postoperative care and outcome assessment

Settings and conduct
The study will be conducted on patients with diabetes type 1 or 2, in Shariati hospital, Tehran for 1 year. Patients will be divided into 2 groups receiving dextrose 10%(intervention group) or normal saline(control group) 3 times per week for 1 month. The study is triple blinded and none of the patients, study investigators and data assessors know the type of treatment given to the patient.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Patients older than 18 years Patients with type 1 and 2 diabetes mellitus HbA1C = 7-10% Ability to understand and collaborate during the study At least one chronic ulcer lasting for more than 4 weeks Ulcer in plantar or dorsal surface of foot or in the malleolus Ankle-brachial index = 0.7 - 1.2 in ischemic ulcers Wagner grade 2, 3 Wound area 1-20 cm2 None of the patients had received glucocorticoid, estrogen or other drugs interfere healing process within the past 1 month

Intervention groups
The study will have 2 groups. One group will receive dextrose 10% as intervention group and the other will utilize injecting normal saline, as control group.

Main outcome variables
Wound area, pain score, ABI (ankle-brachial index), WBC(white blood cell), BS(blood glucose), ESR(erythrocyte sedimentation rate), CRP(C-reactive protein)

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20220424054636N1**
Registration date: **2022-05-17, 1401/02/27**
Registration timing: **registered_while_recruiting**

Last update: **2022-05-17, 1401/02/27**
Update count: **0**

Registration date
2022-05-17, 1401/02/27

Registrant information

Name
Asma Mafhoumi

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 21 6601 9264

Email address
asmamafhoumi@yahoo.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-05-14, 1401/02/24

Expected recruitment end date
2023-05-14, 1402/02/24

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title

Comparing the effect of Prolotherapy with Placebo, in patients with diabetic foot ulcer

Public title
Studying the Effect of prolotherapy in diabetic foot ulcer
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Age > 18 years old Patients with confirmed type 1 or 2 diabetes mellitus HbA1C = 7-10% Ability to understand and collaborate during the study Having at least one chronic ulcer lasting for more than 4 weeks Plantar or dorsal or malleolar ulceration ABI = 0.7 - 1.2 in ischemic ulcers Ulcers with Wagner grades 2, 3 Ulcers with wound area = 1-20 cm2 None of the patients had received glucocorticoid, estrogen, or other drugs that interfere healing process within the past 1 month Patients who signed the informed consent
Exclusion criteria:
Patients with a history of malignancy or coagulopathy GFR < 30 ml/min/1.73m2 Albumin level < 3.5 g/dl Pregnancy
Age
From **18 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
We used the block randomization method and our randomization unit was individual. Random blocks were chosen using the site www.sealedenvelope.com. Block sizes were 4, 6, and 8 and each block had both intervention A, and B equally.
Blinding (investigator's opinion)
Triple blinded
Blinding description
Our study was designed triple blinded and none of the patient, study investigator and data analyzer knew the type of intervention given to the patient. The drug will be provided by someone not involved in the study so the executors will be blind about the type of treatment.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Research Ethics Committee of Tehran University of Medical Sciences
Street address
No. 48, Mojallal alley, Jeyhoun street, Tehran, iran
City
Tehran
Province
Tehran
Postal code
1344913686
Approval date
2022-04-03, 1401/01/14
Ethics committee reference number
IR.TUMS.DDRI.REC.1401.001

Health conditions studied

1

Description of health condition studied
Diabetic foot ulcer
ICD-10 code
E08
ICD-10 code description
Diabetes mellitus due to underlying condition

Primary outcomes

1

Description
Wound area
Timepoint
Before intervention and 7, 14, 21 and 28 days after intervention
Method of measurement
Digital imaging to measure wound area

2

Description
Patient's pain scale
Timepoint
Before intervention and 7, 14, 21 and 28 days after intervention
Method of measurement
Visual Analogue Scale

Secondary outcomes

1

Description
White blood cell
Timepoint
Before and after intervention
Method of measurement
Complete blood cells test

2

Description
Erythrocyte sedimentation rate
Timepoint
Before and after intervention
Method of measurement
Quantitative measurement of erythrocyte sedimentation rate in blood

3

Description
C-reactive protein
Timepoint
Before and after intervention
Method of measurement
Quantitative measurement of C-reactive protein in blood

4

Description
Blood glucose
Timepoint
Before and after intervention
Method of measurement
Glucometry

5

Description
Ankle - Brachial index
Timepoint
Before and after intervention
Method of measurement
Doppler sonography

Intervention groups

1

Description
Intervention group: injection of 1ml dextrose 10% per each cm2 of wound up to 10ml, 3 times per week, in the base and periphery of wound
Category
Treatment - Drugs

2

Description
Control group: injection of 1ml normal saline per each cm2 of wound up to 10ml, 3 times per week, in the base and periphery of wound
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Shariati hospital
Full name of responsible person
Asma Mafhoumi
Street address
Tehran, North Kargar St., Jalal Al-Ahmad Intersection, Shariati Hospital
City
Tehran
Province
Tehran
Postal code
1411713135
Phone
+98 21 8490 1000
Fax
+98 21 8863 3039
Email
shariatihosp@tums.ac.ir
Web page address
http://shariati.tums.ac.ir/

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Akbar Fotoohi
Street address
Floor 6, Central University Organization, Quds Street, Keshavarz Boulevard
City
Tehran
Province
Tehran
Postal code
1417613151
Phone
+98 21 8163 3698
Email
vcr@tums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Tehran 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

Asma Mafhoumi

Position

Student

Latest degree

Bachelor

Other areas of specialty/work

Orthopedics

Street address

No.48, mojallal Avenue, jeyhoon Street, Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1344913686

Phone

+98 21 6601 9264

Fax

Email

asmamafhoumi@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

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Person responsible for updating data

Contact

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be 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

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be 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