

Clinical Trial Protocol

Iranian Registry of Clinical Trials

14 Jul 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
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 updating data

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

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