

Clinical Trial Protocol

Iranian Registry of Clinical Trials

14 Jul 2026

Comparison of the efficacy of atmospheric pressure plasma and common treatment in diabetic patients with foot ulcer

Protocol summary

Study aim

The Study of the Effectiveness of Atmospheric Pressure Plasma in the Improvement of Diabetic Wounds

Design

Clinical trial with a double-blind, randomized, controlled group, based on patients with diabetic foot ulcers with a parallel group

Settings and conduct

Razi Hospital affiliated to Tehran University of Medical Sciences will be considered as a research environment. At first, qualified people will enter the study after consent is obtained consciously. Using random allocation method, they are divided into two groups. The intervention group is exposed to atmospheric pressure plasma for 6 weeks. The control group is under common treatment. This is a double-blind study. Clinical participants and caregivers have been blinded and The only expert on plasma radiation is aware of this .

Participants/Inclusion and exclusion criteria

Inclusion criteria : Type 2 diabetes - Has diabetic ulcer size (1-30) cm² - Wound do not have more than 2 years of age - Hb1Ac < 10% - Do not have bone infection - Patient over 18 years of age exclusion criteria : Patients with addiction or alcohol abuse - Patients with psychological problems or dissatisfaction with the company in the study - Patients with diabetic nephropathy - Localized necrosis /Gangrene - Hb1Ac > 10%

Intervention groups

The intervention group includes diabetic patients with foot ulcers,exposed to atmospheric pressure plasma . The control group includes diabetic patients with foot ulcers that are under common treatment.

Main outcome variables

Wound area; Exudate levels ; Type of wound tissue

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20181012041317N1**

Registration date: **2018-11-05, 1397/08/14**

Registration timing: **prospective**

Last update: **2018-11-05, 1397/08/14**

Update count: **0**

Registration date

2018-11-05, 1397/08/14

Registrant information

Name

Shirin Samsavar

Name of organization / entity

Shahid beheshti university

Country

Iran (Islamic Republic of)

Phone

+98 21 2990 4017

Email address

shirinsamsavar@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-11-26, 1397/09/05

Expected recruitment end date

2018-12-26, 1397/10/05

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the efficacy of atmospheric pressure plasma and common treatment in diabetic patients with

foot ulcer

Public title
The effect of atmospheric pressure cold plasma in patients with diabetic foot ulcer

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
 Type 2 diabetes Has diabetic ulcer size (1-30) cm2
 Wound do not have more than 2 years of age. Hb1Ac < 10% Do not have bone infection Patient over 18 years of age
Exclusion criteria:
 Patients with addiction or alcohol abuse Patients with psychological problems or dissatisfaction with the company in the study Patients with diabetic nephropathy Localized necrosis /Gangrene Hb1Ac > 10%

Age
From **18 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Participant
- Care provider

Sample size
Target sample size: **20**

Randomization (investigator's opinion)
Randomized

Randomization description
Randomization method: use block; Random unit: Individual; Randomization tool: Statistical software

Blinding (investigator's opinion)
Double blinded

Blinding description
The doctor and the patient are unaware of the grouping, and only the plasma radiation expert knows.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids
empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Tehran University of Medical Sciences

Street address

Vice-chancellor for Research of Tehran University of Medical Sciences, 205th room, 1st floor, Education Bldg, Poursina st.

City
Tehran

Province
Tehran

Postal code
1416634391

Approval date
2018-05-23, 1397/03/02

Ethics committee reference number
IR.TUMS.MEDICINE.REC.1397.010

Health conditions studied

1

Description of health condition studied

Diabetic Foot Ulcer

ICD-10 code

E11.5

ICD-10 code description

Type 2 diabetes mellitus with peripheral circulatory complications

Primary outcomes

1

Description

Wound area

Timepoint

After selecting the patient during the 12 sessions (weekly 2 sessions) in the first session (before the treatment) and the end of session 6 and 12, the area of the wound is checked.

Method of measurement

Take digital photo with ruler - Push score - Calculate area with imagej software

2

Description

Exudate levels

Timepoint

At the first session (before treatment) and the end of session 6 and 12 , a microbial culture of the wound secretions is performed

Method of measurement

with standard method swap - Push score

3

Description

Type of wound tissue

Timepoint

The first session (before treatment) and the end of session 6 and 12 are checked.

Method of measurement

Take digital photo - Push score

Secondary outcomes

1

Description

Quality of life

Timepoint

Before treatment - the end of treatment - 8 weeks after the end of treatment

Method of measurement

Diabetes Quality of Life (DQOL) Questionnaire

2

Description

side effects of cold plasma radiation on the patient

Timepoint

During and after radiation of the plasma

Method of measurement

Ask the patient about possible symptoms and see the wound's position

Intervention groups

1

Description

Intervention group: In this study , plasma torch will be used as the source of helium gas jet plasma. The plasma is created in 2 days a week, and each time for 5 minutes on the wound will be directly exposed.

Category

Treatment - Other

2

Description

Control group: In this group only standard wound care treatments such as debridement, dressing, antibiotic administration, and patient education, and no plasma radiation, will be used.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Razi Hospital

Full name of responsible person

Dr. Hamid-Reza Mahmoudi

Street address

Razi Skin Hospital, Razi Ave., Vahdate eslami Ave.,
Hafiz St.

City

Tehran

Province

Tehran

Postal code

1199663911

Phone

+98 21 5563 0174

Email

hr_mahmoody@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid beheshti university

Full name of responsible person

Dr . Babak shokri

Street address

Shahid Beheshti University - Velenjak st , Tehran, Iran

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Province

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Postal code

1983969411

Phone

+98 21 2990 2788

Email

babakshokri@yahoo.com

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Shahid beheshti university

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

Full name of responsible person

Shirin samsavar

Position

student

Latest degree

Master

Other areas of specialty/work

plasma physics

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Daneshjou Blvd , District , Velenjak

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1983969411

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Email

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

DR . Hamid-reza mahmoudi

Position

Associate Professor

Latest degree

Specialist

Other areas of specialty/work

Dermatology

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Person responsible for updating data

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Full name of responsible person

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Other areas of specialty/work

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shirinsamsavar@gmail.com

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

Yes - There is 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

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

Data collected for the primary and secondary outcome measurements .

When the data will become available and for how long

startting 9 month after publication until 5 years later

To whom data/document is available

For researchers working in academic and scientific institutions

Under which criteria data/document could be used

Use of data and documentation is not allowed in any article, thesis, etc.

From where data/document is obtainable

The applicant for documentation can be contacted by email with person responsible for scientific inquiries and person responsible for general inquiries . person responsible for scientific inquiries : Dr. Hamid Reza Mahmoudi hr_mahmoody@yahoo.com person responsible for general inquiries : shirin samsavar shirinsamsavar@gmail.com

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

By sending an email, it can receive data.

Comments