Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Use of cold atmospheric argon plasma to heal and accelerate the healing of wounds of infectious diabetic foot

Protocol summary

Study aim

Our aim in this study was to investigate the ability of atmospheric pressure plasma to improve the quality, speed of healing and healing of diabetic wounds in the human phase using argon jet, which is also more economical than helium jet.

Design

The clinical trial has two groups of control and intervention with parallel, non-blind, randomized groups and also in the third phase of the clinical trial study. Block Randomization table method was used for randomization.

Settings and conduct

Endocrinology and metabolism research institute of Tehran university of medical science.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: 1- The patient has G2 or G3 diabetic foot ulcer according to Wagner classification. 2- The patient has an infectious diabetic foot ulcer. (Symptoms such as redness, pain, discharge, and tenderness) 3- There is no age or sex limit in this study. Exclusion Criteria: 1- Getting cancer 2- Taking immunosuppressive drugs 3- Pregnant patients 4- Patients with a bone infection (Osteomyelitis) 5- The patient's unwillingness

Intervention groups

Patients participating in this study were randomly divided into two groups using the Block Randomization table method. Patients in the control group receive standard treatment including washing, debridement, dressing, appropriate antibiotics, and offloading. In the intervention group, in addition to standard treatment, plasma irradiation is used for 2 minutes per session for 4 consecutive weeks.

Main outcome variables

Rate (percentage) of wound size reduction and wound healing time (granulation tissue formation and epithelialization)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20080904001199N5**
Registration date: **2020-10-15, 1399/07/24**
Registration timing: **prospective**

Last update: **2020-10-15, 1399/07/24**
Update count: **0**

Registration date

2020-10-15, 1399/07/24

Registrant information

Name

Mohammad Reza Amini

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 21 8822 0038

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-10-22, 1399/08/01

Expected recruitment end date

2021-09-22, 1400/06/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Use of cold atmospheric argon plasma to heal and accelerate the healing of wounds of infectious diabetic foot

Public title
The effect of argon plasma in the treatment of diabetic foot ulcers
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
G2 or G3 grade diabetic foot ulcer according to Wagner classification Symptoms of the infection in the wound (erythema, pain, discharge, and tenderness)
Exclusion criteria:
Getting cancer Taking immunosuppressive drugs Pregnant patients Patients with bone infection
Age
From **18 years** old to **75 years** old
Gender
Both

Phase
3
Groups that have been masked
No information
Sample size
Target sample size: **80**
Randomization (investigator's opinion)
Randomized
Randomization description
In this study, patients will be randomly divided into two groups of control with standard treatment and intervention group with standard treatment plus plasma radiation based on the Blocked randomization table.
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
Endocrinology and metabolism research institute of Tehran university of medical science.
Street address
Shariati Hospital, Floor 5, N Kargar
City
Tehran
Province
Tehran
Postal code
1411713135
Approval date
2020-09-28, 1399/07/07
Ethics committee reference number
IR.TUMS.EMRI.REC.1399.037

Health conditions studied

1

Description of health condition studied
Infectious diabetic foot ulcers
ICD-10 code
E11.4
ICD-10 code description
Type 2 diabetes mellitus with neurological complications

Primary outcomes

1

Description
Wound area
Timepoint
The wounds of all participants will be photographed in each session.
Method of measurement
Using a digital camera with a ruler and photo analysis in the software environment, the wound area is examined.

Secondary outcomes

1

Description
Reducing bacterial load
Timepoint
Samples of wound secretions are taken at the beginning of the study, mid-treatment and at the end of the study for microbial culture.
Method of measurement
The sample is taken from the depth of the wound using a standard method and the use of a swab.

2

Description
Reduction of wound area
Timepoint
At each visit, the wound area is measured.
Method of measurement
Wound dimensions are measured using a ruler and wound photos are analyzed using software.

Intervention groups

1

Description
Intervention group: In this group, according to the random selection of patients with diabetic foot ulcers

after explaining how to treat after observing the principles of treatment (washing and cleaning the wound, wound debridement, if necessary, offloading and finally appropriate dressing) with argon plasma Wipe the wound surface for 2 minutes. The treatment intervals are one week and finally the patient leaves the plan within 1 month of follow-up.

Category

Treatment - Devices

2

Description

Control group: In this group, after accurate wound evaluation, standard treatments including wound washing, wound debridement, use of appropriate antibiotics, offloading (if necessary) and use of appropriate wound dressing are considered.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Diabetes Clinic - Diabetes Research Center

Full name of responsible person

Dr. E. Nasli

Street address

Endocrinology and metabolism research institute of Tehran university of medical sciences, End of Jalal Al-Ahmad highway

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

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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

Tehran University of Medical Sciences

Proportion provided by this source

50

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

2

Sponsor

Name of organization / entity

Laser and Plasma Research Institute of Shahid Beheshti university

Full name of responsible person

Dr. Babak Shokri

Street address

Shahid Beheshti University, Shahid Shahriari Square, Daneshjou Boulevard, Shahid Chamran Highway, Tehran, Iran

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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

Laser and Plasma Research Institute of Shahid Beheshti university

Proportion provided by this source

50

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
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Mohammad Reza Amini
Position
GP and DF PhD
Latest degree
Medical doctor
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Person responsible for updating data

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Bachelor
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
Due to ethical considerations
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
No - There is not 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
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available