# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

22 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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**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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Tehran

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## Sponsors / Funding sources

**1**

**Sponsor**

**Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

Neda Mehrdad

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neda1340@yahoo.com

**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

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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**
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Tehran University of Medical Sciences
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Mohammad Reza Amini
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## Person responsible for scientific inquiries

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## Person responsible for updating data

**Contact**
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Laser and Plasma Research Institute of Shahid Beheshti university
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student
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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