

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Evaluation of the effectiveness of cold plasma radiation in the treatment of infected wounds diabetic foot and molecular mechanisms related

Protocol summary

Reduce bacterial load and the size of the wound and
Formation of granulation tissue

Study aim

Determination of the Effect of Plasma Radiation on the Treatment of Diabetic Foot Infections and decrease of bacterial load and ulcer size

Design

This is a double-blind clinical trial. Diabetic patients referred to diabetic clinics with 40 cases of diabetic foot ulcer infection are selected based on entry and exit criteria. After completing the informed consent form and the questionnaire, diagnostic tests are performed for all patients. Blood samples are taken from all patients for the following tests: FBS, HbA1c, Cr. , BUN, CBC, CRP, Chol, TG, LDL, HDL, ALT, AST, ALK Ph The standard measures are taken to treat the wounds of diabetic patients: 1) Normal saline wash and wound debridement 2) Appropriate antibiotic administration 3) Reduced wound pressure 4) Suitable dressing 5) Patient training 6) Patient's glycemic control. Sampling of wound secretions is performed to perform cytokine tests or angiogenesis factors before and during the third week. Then, in both groups, the wound of the scar tissue is wound in the standard method at regular intervals of the week. A cold jet plasma rifle will be used as the source for the jet plasma with helium gas. The plasma is created in 1 day intervals and each time for 5 minutes on the wound will be directly exposed.

Settings and conduct

Diabetes Clinic - Diabetes Research Center

Participants/Inclusion and exclusion criteria

The criteria for entering the design are: 1) Grade 2 wounds according to Wagner and Texas classification and stage B 2; and 3) Wound type: Neuropathy, neuroischaemia Exit criteria: 1) Pregnancy 2) Lactation 3) Cancer diagnosed and treated 4) Under 18 years of age 5) Dementia 6) Immunosuppressive drugs 7) Gangrene wounds 8) Ischemic ulcer 9) Non-cooperation

Intervention groups

Diabetic Patients with infected foot ulcers

Main outcome variables

General information

Reason for update

Acronym

پلاسمای سرد و زخم پای دیابتی

IRCT registration information

IRCT registration number: **IRCT20080904001199N2**

Registration date: **2018-04-07, 1397/01/18**

Registration timing: **retrospective**

Last update: **2018-04-07, 1397/01/18**

Update count: **0**

Registration date

2018-04-07, 1397/01/18

Registrant information

Name

Mohammad Reza Amini

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 21 8822 0038

Email address

mramini@tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-04-04, 1396/01/15

Expected recruitment end date

2017-10-07, 1396/07/15

Actual recruitment start date

2017-04-04, 1396/01/15

Actual recruitment end date

2017-10-07, 1396/07/15

Trial completion date
empty

Scientific title
Evaluation of the effectiveness of cold plasma radiation in the treatment of infected wounds diabetic foot and molecular mechanisms related

Public title
Effect of cold plasma on diabetic foot ulcers

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
 Diabetic patient with infected ulcer DFU grade 2
 Neuropathic and Neuroischemic Ulcer ABI>0.8 , ABI<1.3
Exclusion criteria:
 Not patient compliance Ischemic ulcers Pregnancy
 cancer Dementia age< 18 Immunosuppressive therapy
 Gangrene Ulcer

Age
From **18 years** old to **70 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size
 Target sample size: **40**
 Actual sample size reached: **40**

Randomization (investigator's opinion)
Randomized

Randomization description
 The first step in the random process is to create a random sequence. The second step after creating a random sequence is to hide the generated sequence. To use the random number table, we must first determine the number of the table to read. The second is to consider numbers for different groups (for example, pair numbers for intervention A and individual numbers for intervention B, then hand over one of the numbers and move in one of the directions predetermined and record the numbers We assign to different groups. Blocking is usually used to create a balance in the number of specimens assigned to each of the groups studied, for example, in blocks of 4 that have two allocations to the intervention group and two allocations to the control group is taken.

Blinding (investigator's opinion)
Double blinded

Blinding description
 Doctors and nurses, as well as the patient, are unaware of the grouping, and the only expert on plasma radiation is aware of this. Patients do not see the ulcer during plasma radiation

Placebo

Used

Assignment
Single

Other design features
NO

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Endocrinology and Metabolism Research Institute

Street address

Dr. Shariati Hospital , 5th floor

City

Tehran

Province

Tehran

Postal code

1411413137

Approval date

2016-03-02, 1394/12/12

Ethics committee reference number

IR.TUMS.EMRI.REC.1395.0089

Health conditions studied

1

Description of health condition studied

Diabetic Foot Ulcer

ICD-10 code

E11.4

ICD-10 code description

Type 2 diabetes mellitus with neurological complications

Primary outcomes

1

Description

Area of ulcer

Timepoint

After selecting a patient for up to 3 weeks in each visit (one day in between), the size of the patient's wound is measured.

Method of measurement

take a photo with ruler and analysis it

2

Description

microbial colony count

Timepoint

Up to 3 weeks after the patient's choice, once a week, a microbial culture of the wound secretions is performed

Method of measurement

with standard method swap

3

Description

cytokines and growth factors

Timepoint

at the first and end of third week

Method of measurement

128/5000Samples from ulcerous secretions are taken with pasteurized sterile pipettes and then by ELISA, cytokines and growth factors are measured.

Secondary outcomes

1

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

In this study, a cold jet plasma rifle machine will be used as a source of helium gas jet plasma. The plasma is created in 1 day intervals 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

Diabetes Clinic - DRC

Full name of responsible person

Dr. Nasli

Street address

North Kargar st., Shahrivar St.

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2222233333

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Endocrinology and Metabolism Research Institute

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

Endocrinology and Metabolism Research Institute

Proportion provided by this source

70

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

Plasma physics research Center

Full name of responsible person

Dr. ghorannevis

Street address

Azad university , central organization, research science Unit

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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

Plasma physics research Center

Proportion provided by this source

30

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

Endocrinology and Metabolism Research Institute

Full name of responsible person

Mohammad Reza Amini

Position

GP and DF PhD Student

Latest degree

Medical doctor

Other areas of specialty/work

General Practitioner

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Latest degree

Medical doctor

Other areas of specialty/work

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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

ethical

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