Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

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

Protocol summary

Study aim
The Study of the effectiveness of cold atmospheric plasma in healing diabetic foot ulcers

Design
Clinical trial with control group, with parallel groups, single blind, randomized, on 52 patients. Random Allocation software was used for randomization.

Settings and conduct
The environment of this research is the Razi educational and therapeutic center of Rasht. First, the eligible people will enter the study based on the entry criteria, after obtaining informed consent, and will be divided into two groups using the random allocation method. The people in the intervention group will be exposed to cold atmospheric plasma radiation for 2 weeks (6 sessions). And the people in the control group are subjected to common diabetic foot ulcer treatments along with placebo. This study is single-blind. Participants in this study are blinded.

Participants/Inclusion and exclusion criteria
Inclusion criteria include: age range from 18 to 80 years, having type 1 or 2 diabetes, having a grade 1 or 2 wound in the lower limb based on the Wagner scale. The exclusion criteria include: having a hemoglobin A1C higher than 10%, , pregnant and lactating women, a history of cancer, having artificial pacemakers, having a history of epilepsy.

Intervention groups
The intervention group includes patients with diabetic foot ulcers, in which each ulcer is treated with cold plasma three times a week and each time for two minutes during 2 weeks (6 sessions). The control group in this study includes patients with diabetic foot ulcers, in which each ulcer is treated three times a week and for two minutes each time during 2 weeks (6 sessions) with placebo, which is an inactive plasma device probe.

Main outcome variables
Wound area, wound degree, side effects caused by plasma radiation

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20181002041205N2**
Registration date: **2023-09-12, 1402/06/21**
Registration timing: **prospective**

Last update: **2023-09-12, 1402/06/21**
Update count: **0**

Registration date
2023-09-12, 1402/06/21

Registrant information

Name
fatemeh jafaraghaee

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 13 3355 5058

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jafaraghaee@gums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-10-02, 1402/07/10

Expected recruitment end date
2023-12-01, 1402/09/10

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title

Comparison of the efficacy of cold atmospheric 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:
age range from 18 to 80 years having type 1 or type 2 diabetes having a grade 1 or 2 wound in the lower limb based on the Wagner scale
Exclusion criteria:
having a hemoglobin A1C higher than 10%. simultaneous use of other treatment methods such as vacuum therapy, maggot therapy, PRP or platelet-rich plasma. pregnant and lactating women. a history of cancer. under Being treated with chemotherapy drugs or immunosuppressive drugs. having artificial pacemakers. having a history of epilepsy . participating in other studies are concurrent.
Age
From **18 years** old to **80 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Participant

Sample size
Target sample size: **52**
Randomization (investigator's opinion)
Randomized
Randomization description
using block, randomization unit: individual, randomization tool: Random Allocation software. The randomization tool in this study will be Random Allocation software, this software is capable of creating random sequences using the block method.In order to hide the allocation in this research, random allocation concealment is used, which refers to the method used to perform a random sequence on the participants in the study, in such a way that the allocated group is not known before the allocation of the individual.The intended method is to use sealed opaque letter envelopes with a random sequence. In this method, each random sequence created is recorded on a card and the cards are placed inside the letter envelopes in order. In order to maintain a random sequence, the outer surface of the envelopes is numbered in the same order. Finally, the lid of the letter envelopes is glued and placed in a box . At the time of starting the registration of participants, based on the order in which eligible participants entered the study, one of the envelopes will be opened and the assigned group of that participant will be revealed.
Blinding (investigator's opinion)
Single blinded
Blinding description
Patients in this study are blinded and are not aware of receiving placebo or plasma treatment for the purpose of blinding.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Guilan University of Medical Science
Street address
Office for Research and Technology, Shahid Siadati St, Namjoo St, Rasht
City
Rasht
Province
Guilan
Postal code
4188794755
Approval date
2023-08-09, 1402/05/18
Ethics committee reference number
IR.GUMS.REC.1402.280

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 circulatory complications

Primary outcomes

1

Description
Wound area
Timepoint
The measurement is done on the first day of the visit and after every intervention and two days after the last intervention (days 1, 3, 5, 7, 9, 11 and 13).
Method of measurement
Take digital photo with ruler - Calculate area with imagej software

2

Description
wound grade
Timepoint
The initial grade of the wound at the beginning of the study was first determined by the Wagner criterion and at the end of the study it was also determined based on this criterion.
Method of measurement
According to Wagner's criterion

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
Intervention group: The intervention group in this study will receive all the standard care for diabetic foot ulcers, which includes the prescription of appropriate antibiotics (if possible, the same antibiotics are used in the test and control groups), blood sugar control, and site care. wound (intermittent washing, dressing, debridement, and patient education). In the intervention group, each wound is treated with cold plasma three times a week and for two minutes each time (according to the recommendation of the manufacturer of the device) during 2 weeks (6 sessions). Cold plasma will be produced by DBD plasma device where plasma is created by electric discharge with dielectric barrier.
Category
Treatment - Devices

2

Description
Control group: The control group in this study includes patients with diabetic foot ulcers who will receive all the standard care of diabetic foot ulcers, included proper antibiotics, glycemic control, and local wound care Also, each wound is treated three times a week for two minutes during 2 weeks (6 sessions) with a placebo, which is the probe of the inactive plasma device along with the pre-recorded sound of the device.
Category
Treatment - Devices

Recruitment centers

1

Recruitment center
Name of recruitment center
Razi Educational and Treatment Center of Rasht
Full name of responsible person
Dr.Behrang Motamed
Street address
Rasht,Sardare Jangal Blvd,Razi Educational and Treatment Center
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Rasht University of Medical Sciences
Full name of responsible person
Dr.Fatemeh jafaraghaee
Street address
Daneshju Ave, Hamidian, Shahidbeheshti Highway, Rasht
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Email
jafaraghaee@gums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Rasht 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
Rasht University of Medical Sciences

Full name of responsible person
Nima Rafiee

Position
student

Latest degree
Bachelor

Other areas of specialty/work
Nursery

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Person responsible for scientific inquiries

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Position
Associate professor

Latest degree
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Other areas of specialty/work
Nursery

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Person responsible for updating data

Contact

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Position
student

Latest degree
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Other areas of specialty/work
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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 12 month after publication until 5 years later

To whom data/document is available
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 person requesting to receive the documents can contact the person in charge of scientific accountability and general accountability of the project via email. Scientific accountability: Dr. Fatemeh Jafar Aghaee jafaraghaee@gums.ac.ir General answer: Nima Rafiee Liavoli liavolnima2015@gmail.com

What processes are involved for a request to access data/document
By sending an email, it can receive data.

Comments