

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 Jun 2026

Assessment of effect of comprehensive care program on the rate of wound healing in Diabetic Foot Patients treated with ozonotherapy

Protocol summary

Study aim

Determining and comparing wound characteristics and dimensions in the control group before and after the intervention during three months Determining and comparing wound characteristics and dimensions in the intervention group before and after the intervention during three months Comparison of wound characteristics and dimensions in the two groups of intervention and control before and after the intervention during the three

Design

Two-group randomized clinical trial Two-way blind-randomized based random number table with 4 permutations on 94 patients

Settings and conduct

The study was performed at the Ozone Therapy Center of Baqiyatallah Hospital. Patients who are being treated for foot ulcers with ozone bags are randomly divided into two groups In the intervention group, a comprehensive care program is performed and in the other group, no intervention is performed In both groups, on the first day and after each visit, images with equal distance (30 cm) were taken from the wound, the length and width of the wound were recorded using a measuring ruler. The image is taken in such a way that the measuring ruler in the image shows the size of the wound The study will be followed up until the wound heals or finally until three months after the start of the study Blinding will be performed for the physician and caregiver performing ozone therapy and for the findings analyzer

Participants/Inclusion and exclusion criteria

Age 18 to 65 years, with grade 3 diabetic Wegener foot without gangrene, prescribed Ozone bag method for ozone therapy

Intervention groups

Both groups receive ozone twice a week through a special bag for 20 minutes with regular wound washing and dressing changes every 12 hours. In the intervention group, a comprehensive patient care program is

implemented from the very beginning

Main outcome variables

Wound size Wound depth Wound characteristics

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200830048555N1**

Registration date: **2021-05-02, 1400/02/12**

Registration timing: **retrospective**

Last update: **2021-05-02, 1400/02/12**

Update count: **0**

Registration date

2021-05-02, 1400/02/12

Registrant information

Name

Zahra Rooddehghan

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 6692 7171

Email address

rooddehghan@tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-11-21, 1399/09/01

Expected recruitment end date

2021-02-18, 1399/11/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Assessment of effect of comprehensive care program on the rate of wound healing in Diabetic Foot Patients treated with ozonotherapy

Public title
Effect of comprehensive care program on the rate of wound healing in Diabetic Foot Patients

Purpose
Supportive

Inclusion/Exclusion criteria
Inclusion criteria:
18 to 65 years With type one or two diabetes Having grade 3 diabetic foot according to Wegener criteria No pregnancy Not having hyperthyroidism Absence of gangrene in the whole ankle No active osteomyelitis Complete the consent form Prescribe an ozone bag method for ozone therapy There is a wound on one of the legs
Exclusion criteria:
Reluctance to continue research Transformation and treatment model in a more complex way The doctor decides to amputate

Age
From **18 years** old to **65 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Care provider
- Data analyser

Sample size
Target sample size: **41**

Randomization (investigator's opinion)
Randomized

Randomization description
Patients who meet the inclusion criteria enter the study in an accessible manner, The allocation method according to the table of random numbers with 4 permutations will be used. It will be determined that the intervention group with A and the control group with B and according to the patterns obtained from the table of random numbers, sampling will continue until the number of samples reaches the quorum in each group.

Blinding (investigator's opinion)
Double blinded

Blinding description
Physician and clinical care provider Physicians and clinicians do not know which patient group is participating in the comprehensive training program Data Analyzer The obtained data is provided to the statistical analyst through the code of groups one and two

Placebo
Not used

Assignment

Parallel

Other design features

Secondary Ids
empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee in Research School of Nursing and Midwifery and School of Rehabilitation
Street address
School of Nursing Midwifery, Tehran University of Medical Sciences
City
Tehran
Province
Tehran
Postal code
1419733171
Approval date
2020-10-18, 1399/07/27
Ethics committee reference number
IR.TUMS.FNM.REC.1399.113

Health conditions studied

1

Description of health condition studied
Diabetic foot ulcers in ozone therapy
ICD-10 code
E08
ICD-10 code description
Diabetes mellitus due to underlying condition

Primary outcomes

1

Description
Size of diabetic foot ulcers according to Wegener scale
Timepoint
The first day of the examination and re-visit each time
Method of measurement
Take a photo of the wound at a distance of 30 cm while there is a measuring ruler & Wound depth with sterile applicator

2

Description
characteristics of diabetic foot ulcers according to Wegener scale
Timepoint
The first day of the examination and re-visit each time
Method of measurement
Wound characteristic with checklist

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: In the intervention group, a comprehensive care plan for patients is started from the very beginning, and the necessary instructions are given to the patient individually, and a checklist is given in order for the patient to pay attention to the issues that need to be addressed. The patient should record information in it daily so that the level of comprehensive care plan can be checked. Twice a week, each patient will be contacted at a specific time agreed upon by the patient to answer the patient's questions and follow up on a comprehensive care plan

Category

Rehabilitation

2

Description

Control group: without intervention

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Baqiyatallah Ozone Therapy Center

Full name of responsible person

Dr. Morteza Izadi

Street address

No 349, Nosrat st.

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Zrooddehghan@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Mehrnaz Gheranmayeh

Street address

Nosrat st., Tohid sq., Tehran

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fnm@tums.ac.ir

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

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

Tehran University of Medical Sciences

Full name of responsible person

Zahra Rooddehghan

Position

Assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

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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

Confidentiality of participants' information

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

No - There is not a plan to make this available

Data Dictionary

Not applicable

Title and more details about the data/document

Data will not be published

When the data will become available and for how long

After the publication of related articles

To whom data/document is available

Judges who intend to check the accuracy of the study

Under which criteria data/document could be used

Judges who intend to check the correctness of the study

From where data/document is obtainable

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Tohid sq. Tehran I.IRAN 141973317 00989126945759

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

Email the responsible author and explain the reason for requesting the data and receiving the request within two weeks

Comments**Person responsible for updating data****Contact****Name of organization / entity**

Tehran University of Medical Sciences

Full name of responsible person

Zahra Rooddehghan

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

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