Clinical Trial Protocol
Iranian Registry of Clinical Trials

23 Jul 2026

Study on the effects of dry needling on healing outcomes of foot ulcers from diabetes: A randomized clinical trial

Protocol summary

Study aim
Determining the effect of dry needling on the healing of diabetic ulcer using ulcer area and blood flow indicators.

Design
Patients will be included in the research through the available sampling method and will be divided into three groups using the permuted block randomization method using online randomization (www.sealedenvelope.com) A concealed, randomized, blinded, sham controlled clinical trial with a parallel group design of 30 patients

Settings and conduct
Subjects with diabetic foot ulcers will be selected from among those who refer to the diabetes clinic center affiliated with diabetes research institutes of Tehran University of Medical Sciences.The patients will be included in the research through the available sampling method and will be divided into three groups.
Participants and experts who measure the variables.They are not aware of whether they are in the placebo or intervention group.

Participants/Inclusion and exclusion criteria
Patients over 40 years of age with at least one diabetic neuroischemic ulcer resistant to treatment are included in the study. And if people have an infection in the ulcer area and do not consent to participate in the study, they will not be included

Intervention groups
Diabetic patients will be included in the research through the available sampling method and will be divided into three groups with the same sample size in the standard treatment group (blood sugar control, Infection control, proper debridement, new wound dressing) or one of the intervention groups (standard treatment with dry needling or standard treatment with placebo needling) are divided.

Main outcome variables
Ulcer area؛ ulcer depth؛ pain intensity؛ neuropathy intensity؛ viberation perception؛ quality of life

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20230724058903N1**
Registration date: **2023-10-15, 1402/07/23**
Registration timing: **registered_while_recruiting**

Last update: **2023-10-15, 1402/07/23**
Update count: **0**

Registration date
2023-10-15, 1402/07/23

Registrant information

Name
Fatemeh Hasannia

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

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

Expected recruitment end date
2024-07-31, 1403/05/10

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title

Study on the effects of dry needling on healing outcomes of foot ulcers from diabetes: A randomized clinical trial

Public title
Study on the effects of dry needling on healing outcomes of foot ulcers from diabetes: A randomized clinical trial

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
40 years old and above Having at least one diabetic ulcer of the neuroischemic type that is resistant to treatment (after 1 month of standard treatment, it has not yet disappeared) in the area of the feet and fingers. Grade 2 wound on the Wagner scale • 16 cm2 ≥ ulcer size ≥1 cm2 Hba1c< %12

Exclusion criteria:
Foot ulcer with osteomyelitis or bone infection Ulcers that have healed up to 50% within 4 weeks Subjects with immune system deficiency, severe infection in the wound area Having a history of radiotherapy in the last 120 days A history of leg venous thrombosis in the last 6 months History of lymphedema, thrombocytopenia and cellulitis A history of needle phobia

Age
From **40 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Participant
- Care provider
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size
Target sample size: **30**

Randomization (investigator's opinion)
Randomized

Randomization description
The randomization is on the web (www.sealedenvelope.com) and is of block type. This feature helps the researcher to ensure that the number of samples allocated to each of the study groups is equal in cases where intermediate analyzes are needed during the sampling process. A three-group clinical trial of 3 blocks including 10 participants in the intervention group (common treatment with dry needling), 10 participants in the placebo group (common treatment with placebo needling) and 10 participants in the common treatment group (control blood sugar, infection control, proper debridement, new wound dressing).

Blinding (investigator's opinion)
Double blinded

Blinding description
Qualified patients for the study, physiotherapists and wound experts who take the specific tests from the patients at the beginning of the treatment, in the middle and at the end of the treatment do not know whether the patients are placed in the placebo or dry needling group.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Endocrine and Metabolism Research Institute - Tehran University of Medical Scien

Street address
No. 54 , Tandis street, Nelson Mondela street, Tehran

City
Tehran

Province
Tehran

Postal code
1915643584

Approval date
2023-10-08, 1402/07/16

Ethics committee reference number
IR.TUMS.EMRI.REC.1402.074

Health conditions studied

1

Description of health condition studied
Diabetic foot ulcer

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Ulcer area in Image j software

Timepoint
Before the study, one month and three months after the beginning of the study

Method of measurement
Image j software

2

Description
Measuring the depth of the ulcer using a calibrated probe

Timepoint
Before the study, one month and three months after the beginning of the study

Method of measurement
calibrated probe

3

Description
Measuring blood flow using ABI and TBI tests
Timepoint
Before the study, one month and three months after the beginning of the study
Method of measurement
ABI and TBI tests

Secondary outcomes

1

Description
Pain intensity score
Timepoint
Before the study, after first session, one month and three months after the beginning of the study
Method of measurement
Numerical rating scale

2

Description
Neuropathy severity score
Timepoint
Before the study, one month and three months after the beginning of the study
Method of measurement
Michigan and diabetic neuropathy questionnaires

3

Description
Vibration sensation score
Timepoint
Before the study, one month and three months after the beginning of the study
Method of measurement
The Neurothesiometer

4

Description
Quality of life score
Timepoint
Before the study, one month and three months after the beginning of the study
Method of measurement
Wound- QOL questionnaire

Intervention groups

1

Description
Intervention group 1: Standard treatment and Dry needling
Category
Treatment - Devices

2

Description
Intervention group 2: Standard treatment and Sham needling
Category
Treatment - Devices

3

Description
Control group: Standatd treatment (manage blood sugar, infection control, proper debridement, wound dressing)
Category
Treatment - Devices

Recruitment centers

1

Recruitment center
Name of recruitment center
Diabetes clinic center affiliated with diabetes research institutes of Tehran University of Medical
Full name of responsible person
Soofia Naghdi Dorabati
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No. 54 , Tandis street, Nelson Mondela street, Tehran
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Sponsors / Funding sources

1

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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
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
Soofia Naghdi Dorabati
Position
Professor
Latest degree
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Other areas of specialty/work
Physiotherapy
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Person responsible for updating data

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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
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available
Title and more details about the data/document
Only a part of the data, such as the information related to the main result or the like, can be shared. The complete study protocol will be presented in the form of an article. Comprehensive statistical analysis will be done and presented after the completion of data collection. The informed consent form will be provided to the patients.
When the data will become available and for how

long

The access period will start 6 months after the results are published.

To whom data/document is available

It will be available for researchers working in academic and scientific institutions.

Under which criteria data/document could be used

It will be available for researchers working in academic and scientific institutions.

From where data/document is obtainable

Email: naghdi@sina.tums.ac.ir

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

After the request of researchers working in academic and scientific institutions in the form of e-mail, information will be provided to them as soon as possible.

Comments