Clinical Trial Protocol
Iranian Registry of Clinical Trials

23 Oct 2026

The effect of cathodal direct current on the skin temperature and healing in ischemic diabetic foot ulcer, one-blind controlled trial

Protocol summary

Summary

Objective: Diabetic foot ulcer is one of serious complication of diabetes. This study aimed to investigate the effect of cathodal direct current on the skin temperature and accelerates wound closure in the ischemic diabetic foot ulcer. Design: This the one-blind randomized controlled trial conducted in 2014. Setting and conduct: 20 patient with ischemic diabetic foot ulcer were randomly assigned to the electrical stimulation or placebo groups. Participants including major eligibility criteria: Ischemic diabetic foot ulcer; Wagner classification DFU 2; both sex; mild to moderate diabetic neuropath. Exclusion criteria: Skin diseases; osteomyelitis; angioplasty. Intervention: In the electrical stimulation group, cathodal direct current with sensory threshold intensity applied to the wound site for 1 h/day, 3 days/week and for 12 sessions. In the placebo group, the treatment procedure was the same as that described for the electrical stimulation group, but the current intensity was zero. Main outcome (measures variables): Skin temperature in plantar and dorsal foot, before and after intervention, and the wound surface area was measured at 1st, 6th and 12th sessions.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014110819854N1**
Registration date: **2014-12-07, 1393/09/16**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2014-12-07, 1393/09/16

Registrant information

Name

Mohammadreza Asadi

Name of organization / entity

Tarbiat Modares University

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Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Tarbiat Modares University

Expected recruitment start date

2013-11-22, 1392/09/01

Expected recruitment end date

2014-09-12, 1393/06/21

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of cathodal direct current on the skin temperature and healing in ischemic diabetic foot ulcer, one-blind controlled trial

Public title

The effect of electrical stimulation on diabetic foot ulcer

Purpose

Treatment

Inclusion/Exclusion criteria

The main inclusion criteria: Patients with ischemic diabetic foot ulcer; Wagner classification DFU 2; both sex; mild to moderate diabetic neuropathy; 0.7< ankle-brachial index<0.9; HbA1c < 8.2. The main exclusion criteria: Fracture in a lower limb; severe infection;

malignancy; kidney failure; skin diseases; osteomyelitis; angioplasty.

Age
From **40 years** old to **65 years** old

Gender
Both

Phase
2

Groups that have been masked
No information

Sample size
Target sample size: **20**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Single blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Tarbiat Modares University

Street address
Facualty of Medical Sciences, Tarbiat Modares University, Jalal Ale Ahmad Highway

City
Tehran

Postal code

Approval date
2013-07-06, 1392/04/15

Ethics committee reference number
52/2570

Health conditions studied

1

Description of health condition studied
Diabet

ICD-10 code
E10, E11,

ICD-10 code description
Diabetes mellitus

Primary outcomes

1

Description
Skin temperature

Timepoint
Befor and after intervention, 6 and 12 days following onset of intervention

Method of measurement
Centigrade by thermometer

Secondary outcomes

1

Description
Wound surface area

Timepoint
One, 6 and 12 following onset of intervention

Method of measurement
Square centimeter by standard ruler

Intervention groups

1

Description
In the electrical stimulation group, an active carbon rubberized electrode (3 × 4 cm) was placed just outside the ulcer surface area. A dispersive electrode (4 × 6 cm) was placed approximately 20 cm proximal to the active electrode and far from the wound on the proximal region of the leg. The polarity of the active electrode was negative (cathode) during the treatment period. Cathodal direct current with sensory threshold intensity applied to the wound site for 1 h/day, 3 days/week and for 12 sessions.

Category
Treatment - Other

2

Description
In placebo group, an active carbon rubberized electrode (3 × 4 cm) was placed just outside the ulcer surface area. A dispersive electrode (4 × 6 cm) was placed approximately 20 cm proximal to the active electrode and far from the wound on the proximal region of the leg. In the placebo group, the treatment procedure was the same as that described for the electrical stimulation group, but the current intensity was zero.

Category
Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center
Diabetic foot ulcer clinic, Hajar haspital

Full name of responsible person
Mrs. Fathi; Nerse Supervisor

Street address
First of Doctor Beheshti Street, Valiasser Street
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for research, Tarbiat Modares University
Full name of responsible person
Seyid Saeed Mosavian
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Vice chancellor for research, Faculty of Medical Sciences (1), Tarbiat Modares University, Jalal Ale Ahmad Highway
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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
Vice chancellor for research, Tarbiat Modares University
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

Contact
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty