

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 May 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; $0.7 < \text{ankle-brachial index} < 0.9$; $\text{HbA1c} < 8.2$. 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

Faculty 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

Before 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 hospital

Full name of responsible person

Mrs. Fathi; Nerse Supervisor

Street address

First of Doctor Beheshti Street, Valiasser Street

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Web page address**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Tarbiat Modares University

Full name of responsible person

Giti Torkaman

Position

Professor

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Web page address**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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City

Tehran

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****Name of organization / entity**

Tarbiat Modares University

Full name of responsible person

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Position

PhD Student

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Web page address**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