

# 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

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 6691 8531

##### Email address

mohammadreza.asadi@modares.ac.ir

##### 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

**City**

Tehran

**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

**Other areas of specialty/work****Street address**

Physical Therapy Department, Faculty of Medical Sciences, Tarbiat Modares University, Jalal Ale Ahmad Highway

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Torkamg@modares.ac.ir

**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

**Street address**

Vice chancellor for research, Faculty of Medical Sciences (1), Tarbiat Modares University, Jalal Ale Ahmad Highway

**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**

Mohammadreza Asadi

**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*