

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 Jul 2026

Evaluation the effect of transcranial stimulation of the primary motor cortex (M1) in comparison with the transcranial stimulation of the primary motor cortex (M1) and the left dorsolateral prefrontal cortex (F3) on the bio-physiological and psychological status of patients with type 2 diabetes with neuropathic pain

Protocol summary

Study aim

Determining the difference between the effect of transcranial stimulation of cortex M1 with the effect of transcranial stimulation of cortex M1 and F3 on the bio-physiological and psychological status of patients with type 2 diabetes with neuropathic pain

Design

Clinical trial with sham-control group, with parallel groups, double-blind, randomized, on 30 patients. Excel software rand function will be used for randomization

Settings and conduct

The place of the study will be the Bonab Diabetes Association; the study population will be all diabetic patients aged 30 to 55 years with neuropathic pain, who is a member of Bonab Diabetes Association in the summer 2021; Type of blinding: double-blind; The blinding technique: in this study, the transcranial brain stimulation device will be in the postdoctoral researcher's room (Roghayeh Mohammadi) and only she will be aware of the type of intervention for each person. In this study, diabetic patients in all three groups, clinical caregivers and outcome assessors will not know the type of intervention assigned to each group.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Having at least 3 year history of diabetes; Having neuropathic pain; Not receiving psychological treatment since the diagnosis. Non-inclusion criteria: pacemaker

Intervention groups

Intervention group 1: anodic tDCS group of primary motor cortex (M1) , Intervention group 2: anodic tDCS group of primary motor cortex (M1) and the left dorsolateral prefrontal cortex (F3) , Control group: placebo

Main outcome variables

HB a1c content; Glucagon; Insulin; Cortisol, Metanephrine; Normetanephrine; Number of white blood cells; Number of red blood cells; Number of Platelet; Anxiety; Stress; Depression; Pain rate; Sleep Quality; Quality of Life

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210214050363N1**

Registration date: **2021-06-14, 1400/03/24**

Registration timing: **prospective**

Last update: **2021-06-14, 1400/03/24**

Update count: **0**

Registration date

2021-06-14, 1400/03/24

Registrant information

Name

Ahmad Alipoor

Name of organization / entity

Payam-e-Noor University

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-06-21, 1400/03/31

Expected recruitment end date

2021-08-21, 1400/05/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation the effect of transcranial stimulation of the primary motor cortex (M1) in comparison with the transcranial stimulation of the primary motor cortex (M1) and the left dorsolateral prefrontal cortex (F3) on the bio-physiological and psychological status of patients with type 2 diabetes with neuropathic pain

Public title

The effect of tDCS on the treatment of neuropathic pain in diabetics

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

Having at least 3 year history of diabetes Having neuropathic pain Not receiving psychological treatment since the diagnosis Having at least middle school education Being right-handed

Exclusion criteria:

Acute psychological illness Having a pacemaker or intracardiac defibrillator

AgeFrom **30 years** old to **55 years** old**Gender**

Both

Phase

N/A

Groups that have been masked

- Participant
- Care provider
- Outcome assessor

Sample sizeTarget sample size: **30****Randomization (investigator's opinion)**

Randomized

Randomization description

In the present research, randomization will be block, and the randomization unit will be cluster. First, random assignment of patients (30 individuals) to 3 groups (first 10 patients for group A, then 10 patients for group B, and finally 10 patients for group C), is performed using the command to generate integer random numbers ($INT = (RAND) * 30$) the rand function of Excel software. After random assignment of patients to 3 groups, in the next step, random assignment of intervention type to three groups A, B, and C will be performed. Groups (intervention group 1; primary motor cortex stimulation (M1), intervention group 2; primary motor cortex

stimulation (M1) and the left dorsolateral prefrontal cortex (F3), control group; placebo) will be written on three pieces of paper and will be folded, then, by randomly selecting the first paper from the three papers, the type of intervention of group A will be determined by selecting the second paper from the remaining two papers, the type of intervention of group B will be determined and the remaining third paper will determine the type of intervention for group C.

Blinding (investigator's opinion)

Double blinded

Blinding description

This research is done double blindly. Because the device will be in the postdoctoral researcher's room (Roghayeh Mohammadi) and only she will be aware of the type of intervention for each person. In this study, in fact, diabetic patients in all three groups, clinical caregivers (nurse and the researcher's assistant psychologist who will be out of the room), and outcome assessors (both at the association and in the blood test laboratory), will not know the type of intervention assigned to each of the 3 groups.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Payam-e-Noor University

Street address

Graduate Studies Center of Payame Noor University, Safa Alley, Shahnaz Alley, Shahid Haj Mahmoud Nourian St., North Dibaji St., Farmanieh St.

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Province

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Postal code

1953633511

Approval date

2020-12-12, 1399/09/22

Ethics committee reference number

IR.PNU.REC.1399.132

Health conditions studied**1****Description of health condition studied**

Neuropathic pain in diabetes

ICD-10 code

G89.29

ICD-10 code description

Other chronic pain

Primary outcomes

1

Description

Pain score on the McGill Pain Scale

Timepoint

Measurement of pain at the beginning of the study (before the intervention), immediately after the last intervention session, 30 days after the intervention

Method of measurement

the McGill Pain Scale

2

Description

HB A1c

Timepoint

Measurement of HB a1c before the study (last test in two-three months before the intervention), immediately after the last intervention session, 3 months after the intervention

Method of measurement

blood test

3

Description

Glucagon

Timepoint

Measurement of pain at the beginning of the study (before the intervention), immediately after the last intervention session, 30 days after the intervention

Method of measurement

blood test

4

Description

Insulin

Timepoint

Measurement of pain at the beginning of the study (before the intervention), immediately after the last intervention session, 30 days after the intervention

Method of measurement

blood test

5

Description

Cortisol

Timepoint

Measurement of pain at the beginning of the study (before the intervention), immediately after the last intervention session, 30 days after the intervention

Method of measurement

blood test

6

Description

metanephrine

Timepoint

Measurement of pain at the beginning of the study (before the intervention), immediately after the last intervention session, 30 days after the intervention

Method of measurement

blood test

7

Description

normetanephrine

Timepoint

Measurement of pain at the beginning of the study (before the intervention), immediately after the last intervention session, 30 days after the intervention

Method of measurement

blood test

8

Description

white cell count

Timepoint

Measurement of pain at the beginning of the study (before the intervention), immediately after the last intervention session, 30 days after the intervention

Method of measurement

blood test

9

Description

red blood cell count

Timepoint

Measurement of pain at the beginning of the study (before the intervention), immediately after the last intervention session, 30 days after the intervention

Method of measurement

blood test

10

Description

Platelets

Timepoint

Measurement of pain at the beginning of the study (before the intervention), immediately after the last intervention session, 30 days after the intervention

Method of measurement

Platelets blood test

11

Description

Depression

Timepoint

Measurement of pain at the beginning of the study (before the intervention), immediately after the last intervention session, 30 days after the intervention

Method of measurement

The Depression Anxiety Stress Scale- DASS- 42

12

Description

Anxiety

Timepoint

Measurement of pain at the beginning of the study (before the intervention), immediately after the last intervention session, 30 days after the intervention

Method of measurement

The Depression Anxiety Stress Scale- DASS- 42

13

Description

sleep quality

Timepoint

Measurement of pain at the beginning of the study (before the intervention), immediately after the last intervention session, 30 days after the intervention

Method of measurement

Pittsburgh Standard Sleep Quality Questionnaire

14

Description

Quality of Life

Timepoint

Measurement of pain at the beginning of the study (before the intervention), immediately after the last intervention session, 30 days after the intervention

Method of measurement

Questionnaire 36 questions quality of life

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group 1: Primary motor cortical anodic tDCS group of the brain (M1); the group receives 12 sessions, 3 days a week; each session will last 40 minutes (20 minutes left M1 stimulation and 20 minutes right M1 stimulation) in that patients will receive transcranial direct current stimulation (tDCS) for the M1 region with 2 mA electrical current.

Category

Treatment - Devices

2

Description

Intervention group 2: Primary motor cortical anodic tDCS group of the brain (M1) and the anodic tDCS of the left dorsolateral prefrontal cortex (F3); this group receives 12 sessions, 3 days a week. There will be 20 minutes of M1 anodic tDCS (10 minutes left M1 stimulation and 10 minutes of right M1 stimulation) and 20 minutes of F3

region anodic tDCS (left DLPFC) with 2 mA electrical current in each session.

Category

Treatment - Devices

3

Description

Control group: placebo; for this group, the tDCS device, equipped with the default settings for sham stimulation, will provide real stimulation for 20 seconds, then despite remaining of the anode pad on M1 region for 20 minutes and F3 region for 20 minutes, the real stimulation will not happen for these regions.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Bonab County Diabetes Association

Full name of responsible person

Ashraf Sattarfam

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Daneshjoo Street

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Payam-e-Noor University

Full name of responsible person

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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?

No

Title of funding source

Independently by researchers

Proportion provided by this source

100

Public or private sector

Private

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Persons

Person responsible for general inquiries

Contact

Name of organization / entity

PayameNoor university

Full name of responsible person

Rogayeh mohammadi

Position

Postdoctoral researcher

Latest degree

Ph.D.

Other areas of specialty/work

Psychology

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Full name of responsible person

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Person responsible for updating data

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Position

Professor

Latest degree

Ph.D.

Other areas of specialty/work

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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

Undecided - It is not yet known if there will be 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

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document

All data can be shared after de-identification of the individuals.

When the data will become available and for how long

En Access period starts 4 months after publishing the results.

To whom data/document is available

En Both for employed researchers in academic and scientific institutions and for people working in the industry.

Under which criteria data/document could be used

En Any scientific and humanitarian use in order to help to relieve patients' neuropathic pain will be allowed.

From where data/document is obtainable

Refer to Dr. Roghayeh Mohammadi by contact number: 00989141221070 and by email: rogayeh.mohammadi@gmail.com

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

En In case of presenting introduction, reliable documents, and stating the purpose of obtaining the data, the requested data will be emailed to the applicant in a short time.

Comments