

Clinical Trial Protocol

Iranian Registry of Clinical Trials

14 Aug 2026

Evaluation of the effectiveness of TDCS (Transcranial Direct Current Stimulation) in the treatment of hyposmia in patients with Covid-19

Protocol summary

Study aim

Evaluation of the effectiveness of TDCS (Transcranial Direct Current Stimulation) in the treatment of prolonged anosmia and hyposmia in patients with Covid-19

Design

Clinical trial without control group as a case series study on 10 patients.

Settings and conduct

Patients in the physical medicine ward of Hazrat Rasool Akram Hospital undergo four sessions of TDCS (Transcranial Direct Current Stimulation). Patients' sense of smell is measured by SIT (Smell Identification) Test before the intervention and one week after four TDCS sessions.

Participants/Inclusion and exclusion criteria

Age between 18 and 60 years Loss of sense of smell after Covid-19 (anosmia or hyposmia that has not improved for more than a month after the onset of symptoms and with routine treatment) Exclusion criteria also include cases in which the use of the TDCS method is contraindicated: 1. Pregnancy 2. History of chronic pain tolerance conditions 3. Seizures or family history of seizures 3. Implanted metal devices such as pacemakers, metal plate and wire 4. History of brain surgery

Intervention groups

Ten patients who develop a prolonged diminished or loss of sense of smell after Covid 19 disease receive four sessions of TDCS treatment. Patients' sense of smell is measured before the intervention and one week after the intervention, using the SIT test.

Main outcome variables

Olfactory sensitivity

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180205038619N2**

Registration date: **2021-08-30, 1400/06/08**

Registration timing: **prospective**

Last update: **2021-08-30, 1400/06/08**

Update count: **0**

Registration date

2021-08-30, 1400/06/08

Registrant information

Name

Katayoun Moradi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 8896 6574

Email address

katayounmoradi69@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-09-10, 1400/06/19

Expected recruitment end date

2021-10-22, 1400/07/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effectiveness of TDCS (Transcranial Direct Current Stimulation) in the treatment of hyposmia in patients with Covid-19

Public title

Evaluation of the effectiveness of TDCS (Transcranial Direct Current Stimulation) in the treatment of prolonged decreased of sense of smell in patients with Covid-19		2021-01-05, 1399/10/16
Purpose Treatment		Ethics committee reference number IR.IUMS.REC.1399.1089
Inclusion/Exclusion criteria Inclusion criteria: Age between 18 and 60 years Loss of sense of smell after Covid-19 (anosmia that has not improved for more than a month after the onset of symptoms and with routine treatment) Decreased of sense of smell after Covid-19 (anosmia that has not improved for more than a month after the onset of symptoms and with routine treatment) Exclusion criteria: Pregnancy Seizures or family history of seizures Implanted metal devices such as pacemakers, metal plate and wire History of brain surgery		Health conditions studied <u>1</u> Description of health condition studied covid-19 ICD-10 code B34.2 ICD-10 code description Coronavirus infection, unspecified
Age From 18 years old to 60 years old		Primary outcomes <u>1</u> Description Olfactory sensitivity
Gender Both		Timepoint Patients are assessed before the intervention and one week after 4 sessions of TDCS.
Phase N/A		Method of measurement Participants' olfactory sensitivity will be measured by the Smell Identification Test (SIT) . In this method, 24 Iranianized odor such as rose, caffeine, saffron, etc. will be used and a score of 24 will be given, with a score of 19 to 24 being considered the normal range. A score of 14 to 18 is mild microsmia, a score of 10 to 13 is severe microsmia, and a score of 0 to 9 is anosmia.
Groups that have been masked No information		Secondary outcomes empty
Sample size Target sample size: 10		Intervention groups <u>1</u> Description The intervention group will receive a direct current of 2 mA for 20 minutes. In all patients, the anode electrode is located on the left DLPFC region and the cathode electrode is located on the right DLPFC region. The excitation current will be generated by a direct current generator with a maximum current of 4 mA (NeuroStim2 dual channel device). To transmit current, a 35 cm square electrode covered with 0.9% saline-impregnated sponge will be used.
Randomization (investigator's opinion) N/A		Category Treatment - Other
Randomization description		Recruitment centers <u>1</u> Recruitment center Name of recruitment center Hazrat Rasul Akram Hospital
Blinding (investigator's opinion) Not blinded		
Blinding description		
Placebo Not used		
Assignment Single		
Other design features		
Secondary Ids empty		
Ethics committees <u>1</u> Ethics committee Name of ethics committee Ethics committee of Iran University of Medical Sciences Street address Ethics committee, Iran University of Medical Sciences, Hemmat Highway, Tehran City Tehran Province Tehran Postal code 1449614535		
Approval date		

Full name of responsible person

Naseh Yousefi

Street address

Hazrat Rasul Akram Hospital, Niyayesh St, Satarkhan Ave

City

Tehran

Province

Tehran

Postal code

1445613131

Phone

+98 21 6435 1000

Fax

+98 21 6650 2248

Email

nasehusefi@gmail.com

Web page address

<https://hrmc.iums.ac.ir/>

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Iran University of Medical Sciences

Full name of responsible person

Dr. Seyed Ali Javad Mousavi

Street address

5th floor, Headquarters, Iran University of Medical Sciences, Hemmat Highway, Tehran

City

tehran

Province

Tehran

Postal code

1449614535

Phone

+98 21 8214 1201

Email

admins@iums.ac.ir

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

Yes

Title of funding source

Iran 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**

Iran University of Medical Sciences

Full name of responsible person

Katayoun Moradi

Position

Associate Professor of Physical Medicine and Rehabilitation

Latest degree

Specialist

Other areas of specialty/work

Physical Medicine

Street address

Department of Physical Medicine and Rehabilitation, Firuzgar Hospital, Valiasr Square, Tehran

City

Tehran

Province

Tehran

Postal code

1593747811

Phone

+98 21 8214 1229

Email

katayounmoradi69@gmail.com

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

Iran University of Medical Sciences

Full name of responsible person

Katayoun Moradi

Position

Associate Professor of Physical Medicine and Rehabilitation

Latest degree

Specialist

Other areas of specialty/work

Physical Medicine

Street address

Department of Physical Medicine and Rehabilitation, Firuzgar Hospital, Valiasr Square, Tehran

City

Tehran

Province

Tehran

Postal code

1593747811

Phone

+98 21 8214 1229

Email

katayounmoradi69@gmail.com

Person responsible for updating data**Contact****Name of organization / entity**

Iran University of Medical Sciences

Full name of responsible person

Katayoun Moradi

Position

Associate Professor of Physical Medicine and Rehabilitation

Latest degree

Specialist

Other areas of specialty/work

Physical Medicine

Street address

Department of Physical Medicine and Rehabilitation, Firuzgar Hospital, Valiasr Square, Tehran

City

Tehran

Province

Tehran

Postal code

1593747811

Phone

+98 21 8214 1229

Email

katayounmoradi69@gmail.com

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

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

All the patient's data can be shared with privacy in regard to patients name

When the data will become available and for how long

Start accessing 6 months after publishing the results.

To whom data/document is available

For scholars working in academic centers

Under which criteria data/document could be used

It can be analyzed and printed by other people by mentioning the source

From where data/document is obtainable

Dr. Katayoun Moradi katayounmoradi69@gmail.com

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

Upon authentication, data is provided to the individual.

Comments