The effect of transcranial direct current stimulation (tDCS) on diabetes-related visual impairment (diabetic retinopathy)

Submission date 12/01/2021	Recruitment status No longer recruiting	 Prospectively registered [X] Protocol
Registration date 15/01/2021	Overall study status Completed	 [] Statistical analysis plan [X] Results
Last Edited 08/03/2021	Condition category Eye Diseases	[_] Individual participant data

Plain English summary of protocol

Background and study aims

Diabetic retinopathy is a complication of diabetes, caused by high blood sugar levels damaging the back of the eye (retina). It can cause blindness if left undiagnosed and untreated. Proliferative diabetic retinopathy (PDR) is a severe complication of diabetes and the leading cause of preventable blindness.

In the present study, we explored the potential of transcranial direct current stimulation (tDCS) to enhance PDR patients' residual vision.

Transcranial direct current stimulation (tDCS) is a form of brain stimulation that uses constant, low direct current delivered via electrodes on the head.

Who can participate?

Patients clinically diagnosed with PDR who have the capacity to consent participated in this study. They are right-handed and at least 18 years of age during the experiment.

What does the study involve?

Patients were divided into two groups: tDCS and sham group. Patients in the tDCS group received 10 minutes of tDCS stimulation of the part of the brain that process visual information called the visual cortex. Patients in the sham group only received tDCS stimulation for 30 seconds. Visual acuity and ability to discriminate numbers of non-verbal stimuli such as dots (number acuity) were measured before and after stimulation.

What are the possible benefits and risks of participating?

tDCS is a safe and non-invasive method of stimulating the brain. The current is very low (1mA) and will not cause pain or skin burn. Skin irritation is only documented for an extended period of stimulation and higher current intensity. This study expected to improve visual and number acuity of patients who will receive negative current or cathodal tDCS.

Where is the study run from? Nazareth General Hospital in Dagupan City, Pangasinan (Philippines) When is the study starting and how long is it expected to run for? October 2019 to February 2020

Who is funding the study? Investigator initiated and funded

Who is the main contact? Dr Shane Fresnoza, shane.fresnoza@uni-graz.at

Contact information

Type(s) Scientific

Contact name Dr Shane Fresnoza

ORCID ID http://orcid.org/0000-0002-9938-2285

Contact details Goethestrasse 21 Graz Austria 8010 +43 6608474229 shane.fresnoza@uni-graz.at

Additional identifiers

EudraCT/CTIS number Nil known

IRAS number

ClinicalTrials.gov number Nil known

Secondary identifying numbers Nil known

Study information

Scientific Title

Visual cortex transcranial direct current stimulation for proliferative diabetic retinopathy patients: an exploratory randomized trial

Acronym VTDCSPDR

Study objectives

Retinal diseases, including the early stages of diabetic retinopathy, are characterized by high internal noise within the visual pathways which further aggravates impaired visual functions. Cathodal tDCS could reduce neural noise and improve the processing of impaired visual inputs from the damaged retinas of PDR patients.

Ethics approval required

Old ethics approval format

Ethics approval(s)

The clinic where the study is conducted is located in a private, non-research and non-teaching hospital which do not have a formal ethics committee. The patients included in the study were all private patients, who provided informed consent for participation. The study protocol (STUDY PROTOCOL Version 1.1) was approved by the chief of clinics of Nazareth General Hospital in Dagupan City, Pangasinan, Philippines.

Dr Demosthenes Ydia (Chief of Clinics, Nazareth General Hospital, Perez Blvd Dagupan City, Pangasinan, 2433, Philippines; +6309175081288; docbutchydia@yahoo.com)

Study design Double-blinded randomized sham-controlled study

Primary study design Interventional

Secondary study design Randomised controlled trial

Study setting(s) Hospital

Study type(s) Treatment

Participant information sheet No participant information sheet available

Health condition(s) or problem(s) studied

Improving the residual vision of proliferative diabetic retinopathy patients

Interventions

Participants were allocated into either the tDCS group or sham group using block randomization (online Study Randomizer Software (https://www.studyrandomizer.com)).

Participants in the tDCS group received 10 minutes 1 mA cathodal tDCS stimulation of the primary visual cortex.

Participants in the sham group were only stimulated for 30 seconds using the same stimulation parameters.

Measures were taken immediately before and after the stimulation, there was no further follow up.

Intervention Type

Device

Phase Not Applicable

Drug/device/biological/vaccine name(s)

Transcranial direct current stimulation (tDCS)

Primary outcome measure

Visual acuity is measured using the logarithm of the minimum angle of resolution (LogMAR) scores before and after stimulation

Secondary outcome measures

Number acuity measured before and after stimulation using a numerical discrimination task. (Patients were presented with an intermixed of 60 black and white dots. After the stimulus presentation time of 500ms, patients have to indicate whether there were more black or white dots by key presses)

Overall study start date 15/10/2019

Completion date

20/02/2020

Eligibility

Key inclusion criteria

- 1. Clinically diagnosed PDR patients
- 2. Voluntary participation and capacity to consent
- 3. Right-handedness (Edinburgh Handedness Test)
- 4. At least 18 years of age during the experiment

Participant type(s) Patient

Age group Adult

Lower age limit 18 Years

Sex Both

Target number of participants 22

Total final enrolment

22

Key exclusion criteria

1. Other co-morbid conditions such as chronic or residual neurological, psychological, and psychiatric disorders (esp. epilepsy, schizophrenia, mania or depression)

- 2. History of head injury with loss of consciousness
- 3. Intracerebral ischemia/history of cerebral bleeding
- 4. Metal implants in the head and neck area (e.g. post-operative clips)
- 5. Electronic implants (pacemakers, cochlear implant, deep brain stimulator)
- 6. Pregnancy or breastfeeding
- 7. Alcohol or drug addiction
- 8. Local or global aphasia
- 9. Any legal reason why the candidate cannot participate
- 10. Participation in another scientific or clinical study within the last 8 weeks

Date of first enrolment

20/02/2020

Date of final enrolment

20/02/2020

Locations

Countries of recruitment Austria

Austria

Philippines

Study participating centre

Nazareth General Hospital Perez Blvd Pangasinan Dagupan City Philippines 2433

Study participating centre University of Graz

Institute of Psychology Universitätsplatz 2 Graz Austria 8010

Sponsor information

Organisation University of Graz

Sponsor details Institute of Psychology Universitätsplatz 2 Graz Austria 8010 +43 316 380 8541 anja.ischebeck@uni-graz.at

Sponsor type University/education

Website https://psychologie.uni-graz.at/en/

ROR https://ror.org/01faaaf77

Funder(s)

Funder type Other

Funder Name Investigator initiated and funded

Results and Publications

Publication and dissemination plan Planned publication in a high-impact peer-reviewed journal.

Intention to publish date 20/02/2021

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are available from the corresponding author on reasonable request

IPD sharing plan summary Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<u>Protocol file</u>	version v1.1		04/02/2021	No	No
<u>Results article</u>	results	21/02/2021	08/03/2021	Yes	No