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A study of the effect of transcranial magnetic stimulation on cerebellum vermis in treatment-resistant schizophrenia

Submission date
28/05/2020

Recruitment status
No longer recruiting

Registration date
08/06/2020

Overall study status
Completed

Last Edited
04/03/2022

Condition category
Mental and Behavioural Disorders

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

Plain English summary of protocol

Background and study aims
Schizophrenia is a common mental illness that can cause symptoms such as hearing voices and seeing visual hallucinations. Schizophrenia is a lifelong illness that often fails to respond to standard antipsychotic medications or is only partially responsive to the currently available medications. For treatment-resistant schizophrenia patients, there is an urgent need to develop new effective treatments.

Transcranial magnetic stimulation is a noninvasive procedure that uses a coil to generate magnetic fields to stimulate nerve cells in the brain. Evidence suggests that transcranial magnetic stimulation can reduce symptoms of schizophrenia, although trials to date have been limited to a small number of patients and the overall results have been mixed.

The cerebellum is a part of the brain that coordinates voluntary movements such as eye movements, posture, balance, coordination, and speech. Cerebellar abnormalities have been seen in patients with symptoms of schizophrenia, so, therefore, could be a potential therapeutic target for the treatment of schizophrenia. Although the relation of the cerebellar vermis, a part of the cerebellum, to schizophrenia is not clear, it is seen to be smaller in patients with chronic schizophrenia than those without. There has been shown to be short term significant improvement in some symptoms in schizophrenia when high-frequency magnetic stimulation was delivered to the cerebellar vermis.

This study aims to test whether stimulating the cerebellar vermis, using intermittent transcranial magnetic stimulation, can improve the symptoms of schizophrenia in patients with treatment-resistant schizophrenia.

Who can participate?
Adult patients with a diagnosis of treatment-resistant schizophrenia

What does the study involve?
Participants will be randomly allocated to receive either transcranial magnetic stimulation using

a ''Figure of 8 coil'' or a placebo treatment that uses a similar looking coil that does not give magnetic stimulation. For both groups of participants, there will be 2 sessions each day (half an hour apart) for 5 days over 1 week. Each session will last around 3 mins. Participants will have an assessment of their schizophrenia symptoms at the start of the study and these measurements will be repeated at 7 and 21 days

What are the possible benefits and risks of participating?
There are no serious or long-term side effects anticipated. Some participants may develop a headache for which pain relief will be provided.

Where is the study run from?
Shri Guru Ram Rai Institute (India)

When is the study starting and how long is it expected to run for?
From 2019 to 2020

Who is funding the study?
Shri Guru Ram Rai Institute (India)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
SGRR/IEC/1/19

Study information

Scientific Title
Efficacy of adjunctive intermittent theta-burst transcranial magnetic stimulation for treatment-resistant schizophrenia: a randomized placebo-controlled study

Study objectives
There will be significant difference in percentage of change in positive, negative and cognitive symptoms following active intermittent theta burst stimulation as compare to placebo stimulation.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 03/05/2019, Institutional Ethics Committee of Shri Guru Ram Rai Institute of Medical and Health Sciences (Adminstrative building, Patel nagar, Dehradun 248 001 India; +91 0135 2522100; smi.hospital@gmail.com), ref: SGRR/IEC/1/19

Study design
Single-centre, double-blind, placebo-controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Treatment-resistant schizophrenia

Interventions
Participants will be randomized using a lottery method to receive either the intervention of intermittent theta burst transcranial magnetic stimulation to the cerebellar vermis or placebo control.

Intervention arm
Intermittent theta-burst transcranial magnetic stimulation is a non-invasive form of brain stimulation in which a changing magnetic field is used to generate an electric current in a specific area brain (in this trial, the cerebellum-vermis) through electromagnetic stimulation. The MagVenture-MagPro-R30 will be used for stimulation using a coil figure of 8. Participants will receive 2 sessions each day (half an hour apart) for 5 days over 1 week, each session will last around 3 mins, with 600 pulses administered over the cerebellum.

Control arm:
The placebo control will involve the same schedule of Participants will receive 2 sessions each day (half an hour apart) for 5 days over 1 week, and each session will last around 3 mins, but will use the opposite side of Figure of 8 coil use so will not stimulate electrical activity in the brain.

Prior to the intervention participants' schizophrenia symptoms will be assessed and these measurements will be repeated at 7 and 21 days

Intervention Type
Procedure/Surgery

Primary outcome measure
Schizophrenia symptoms measured using the Positive And Negative Symptoms Scale rating done at 0, 7, 21 days

Secondary outcome measures
Schizophrenia symptoms measured using the following at 0, 7, 21 days:
1. Simpson-Angus Extrapyramidal Side-Effects Scale (SAS)
2. Schizophrenia Cognition Rating Scale (SCoRS)
3. Brief Psychiatric Rating Scale (BPRS)
4. Clinical Global Impression (CGI) scale

Overall study start date
15/01/2019

Completion date
15/08/2020

Eligibility

Key inclusion criteria
1. Diagnosis of schizophrenia, according to ICD-10 criteria
2. Treatment-resistant schizophrenia, according to Modified Kane Criteria.
3. Right-handed
4. Normotensive
5. Aged 18 to 59 years

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
40

Total final enrolment
36

Key exclusion criteria
1. Neurological disorders with a history of epilepsy, organ damage, and any neurological procedure
2. Pacemakers or other implanted metal devices
3. Received ECT ≤6 months before enrolment
4. Substance use disorders, except nicotine and caffeine

Date of first enrolment
15/05/2019

Date of final enrolment
15/05/2020

Locations

Countries of recruitment
India

Study participating centre
Shri Guru Ram Rai Institute
Patel Nagar
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Sponsor information

Organisation
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Sponsor type
University/education

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Sponsor type
Hospital/treatment centre

Funder(s)

Funder type
Not defined

Funder Name
Shri Guru Ram Rai University

Results and Publications

Publication and dissemination plan
Planned publication in an international journal.

Intention to publish date
20/07/2020

Individual participant data (IPD) sharing plan
The datasets generated and/or analysed during the current study during this study will be included in the subsequent results publication

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		22/09/2020	04/03/2022	Yes	No