

Pilot study for a new treatment of schizophrenia: a double-blind crossover transcranial magnetic stimulation

Submission date 28/09/2007	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 28/09/2007	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 07/07/2017	Condition category Mental and Behavioural Disorders	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

Study information

Scientific Title

Pilot study for a new treatment of schizophrenia: a double-blind crossover transcranial magnetic stimulation

Study objectives

Does a new transcranial magnetic stimulation (TMS) protocol improve frontal lobe function in schizophrenia patients with severe negative symptoms during fMRI?

The trialists hypothesise that rTMS over the prefrontal cortex and cerebellum using a recently developed protocol (TBS) has a therapeutic effect in patients with schizophrenia via the improvement of frontal lobe function, compared with sham (placebo) treatment.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Study design

Pilot crossover randomised controlled study

Primary study design

Interventional

Secondary study design

Randomised cross over trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied

Schizophrenia

Interventions

12 patients will be randomly assigned to three different treatment conditions:

1. Prefrontal stimulation
2. Cerebellar stimulation
3. Placebo (sham) stimulation

Magnetic stimulation (TBS) will occur on two successive days. Two sessions of TBS will be applied over two successive days (one in day 2, and one just before fMRI in day 3) for each arm (frontal, cerebellar, and sham). Each TBS session (real or sham conditions) comprises two 40-second TBSs with a 10-min break. Patients will undergo symptom, cognitive and psychosocial assessments, before and after the TBS treatment. Throughout the study, all subjects will continue to receive standard care from their responsible consultant psychiatrist.

Before starting TBS, patients will undergo:

1. A medical and psychiatric evaluation
2. Neuropsychological tests to assess concentration and memory abilities and
3. An fMRI brain scan

Patients will receive either real TBS (to the prefrontal cortex or cerebellum) or placebo TBS for approximately 15 minutes (including 10-min break) per day over two successive days.

After treatment, psychiatric evaluation, neuropsychological testing, and fMRI scan will be repeated. TBS treatment and neuropsychological testing will take place within the Academic Unit of Radiology, Royal Hallamshire Hospital, where the MRI scanner is located. If, after the completion of the study, it was determined that TBS was effective in improving cognitive test performance or reducing the severity of psychiatric symptoms, patient who received placebo stimulation will be offered a trial of real rTMS after consulting their responsible consultant psychiatrist.

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

Regional functional brain response measured with functional magnetic resonance imaging (fMRI)

Secondary outcome measures

A variety of standardised psychiatric ratings and neuropsychological tests

Overall study start date

15/05/2006

Completion date

14/05/2008

Eligibility

Key inclusion criteria

1. Adult patients with schizophrenia (ages 18-55 years)
2. Patients will be screened with the Schedule for the Assessment of Negative Symptoms (SANS) (Andreasen, 1983). Patients with severe negative symptoms (defined by score of ≥ 3 in any of SANS sub-scales) will be recruited for this study
3. All participants will be assessed for intelligence using the NART (Nelson, 1991) and handedness with Edinburgh Handedness Inventory (Oldfield, 1971)

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Upper age limit

55 Years

Sex

Both

Target number of participants

12

Key exclusion criteria

1. History of neurological disorder including seizures
2. General medical conditions likely to impair cortical function or haemodynamic response (hypertension or diabetes)
3. Metallic implants (and other contraindications to MR procedures)
4. Established drug or alcohol dependency disorders
5. Estimated IQ less than 75
6. Inability to give an informed consent

Date of first enrolment

15/05/2006

Date of final enrolment

14/05/2008

Locations

Countries of recruitment

England

United Kingdom

Study participating centre

Academic Department of Psychiatry

Sheffield

United Kingdom

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Sponsor information

Organisation

Record Provided by the NHSTCT Register - 2007 Update - Department of Health

Sponsor details

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Sponsor type

Government

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Funder(s)**Funder type**

Government

Funder Name

Sheffield Health and Social Research Consortium

Funder Name

NHS R&D Support Funding

Results and Publications**Publication and dissemination plan**

Not provided at time of registration

Intention to publish date**Individual participant data (IPD) sharing plan****IPD sharing plan summary**

Not provided at time of registration

