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

Submission date	Recruitment status	[ ] Prospectively registered
28/09/2007	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
28/09/2007	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
07/07/2017	Mental and Behavioural Disorders	[ ] 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

Protocol serial number
N0071183075

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

Study type(s)
Treatment

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

Key secondary outcome(s))
A variety of standardised psychiatric ratings and neuropsychological tests

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

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Upper age limit
55 years

Sex
All

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
United Kingdom

England

Study participating centre
Academic Department of Psychiatry
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Sponsor information

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

Funder(s)

Funder type
Government

Funder Name
Sheffield Health and Social Research Consortium

Funder Name
NHS R&D Support Funding

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration