ISRCTN93378085 https://doi.org/10.1186/ISRCTN93378085

# 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

**Contact name**
Dr Kwang Hyuk Lee

**Contact details**
Academic Department of Psychiatry
Longley Centre
Norwood Grange Drive
Sheffield
United Kingdom
S5 7JT
+44 (0)114 226 1511
md4khl@shef.ac.uk

## 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**
Sheffield
United Kingdom
S5 7JT

## 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

### Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|
| Participant information sheet | Participant information sheet | 11/11/2025 | 11/11/2025 | No | Yes |