Effect of high frequency rTMS on negative symptoms and cognitive functioning in schizophrenia

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON25191

Source
Nationaal Trial Register

Brief title
TreNSS

Health condition

- schizophrenia
- negaive symptoms
- transcranial magnetic stimulation
- TMS
- cognitive functioning

Sponsors and support

Primary sponsor: University Medical Center Groningen (UMCG)

Intervention

Outcome measures

Primary outcome

The primary outcome of the study is a significant decline of negative symptoms and cognitive dysfunctioning after bilateral high frequency rTMS treatment of the DLPFC.

Secondary outcome

The secondary outcome of the study is increased cortical activation in the DLPFC after rTMS treatment, measured through a fMRI study.

Study description

Background summary

Negative symptoms in schizophrenia include anhedonia, avolition, alogia and blunted affect. They predict a worse clinical outcome and are often indicative of poorer social, occupational and global outcomes. Currently, no effective treatment exists to improve negative symptoms. The primary objective of the current investigation is to determine the effectiveness of bilateral high frequency rTMS treatment of the dorsolateral prefrontal cortex (DLPFC) on negative symptoms and cognitive dysfunction in patients with schizophrenia. The secondary objective is to study brain activity and changes in brain activity after rTMS through a fMRI study.

Design: Double-blind sham controlled study.

Sample size: 32 patients, 16 in the treatment group and 16 in the sham group.

Study population: All patients should be over 18 years old and should meet the diagnostic criteria for schizophrenia, based on the patient’s medical file and confirmed by a standardized psychiatric assessment. Inpatients as well as outpatients can participate.

Invervention: The rTMS group of 16 patients will receive bilateral rTMS stimulation during 15 days, sessions being given twice daily. The sham group of 16 patients will constitute the placebo group and receive 15 days of bilateral sham stimulation twice daily. The primary outcome of the study is a significant decline of negative symptoms and cognitive dysfunctioning after bilateral high frequency rTMS treatment of the DLPFC. The secondary outcome of the study is increased cortical activation in the DLPFC after rTMS treatment, measured through a fMRI study.

Study objective

Brain activity in people with schizophrenia differs when compared to brain activity of people who do not have this condition. There is evidence that the negative symptoms of schizophrenia are related to reduced cortical activation involving the prefrontal cortex, in particular the activation in the dorsolateral prefrontal cortex (DLPFC) seems to be reduced. The reduced activity in the frontal cortex correlates with the severity of negative symptoms.

Furthermore, several publications on functional neuroimaging literature suggest that hypofrontality in schizophrenia may be related to both negative symptoms and cognitive deficits. Transcranial magnetic stimulation (TMS) is a non-invasive, save method to stimulate the cerebral cortex and thereby alter neuronal function. In TMS a coil, which delivers brief magnetic pulses is placed adjacent to the scalp. The magnetic field passes the skull without hindrance and induces an electric current in certain brain regions. The neuronal pathways may be excited or inhibited, depending on the intensity and frequency of stimulation. Low frequency TMS (1 Hz) decreases brain activity and high frequency TMS (>5 Hz) increases brain activity.
As mentioned earlier, the brain activity in the DLPFC is reduced in people suffering from schizophrenia. Increasing brain activity in the DLPFC by using bilateral high frequency rTMS might therefore prove an effective treatment of negative symptoms and cognitive functioning in schizophrenia.

Study design

Follow-up measurements will be done at 4 weeks and 3 months

Intervention

The rTMS group of 16 patients will receive bilateral high frequency rTMS stimulation during 15 days, sessions being given twice daily.

The sham group of 16 patients will constitute the placebo group and receive 15 days of bilateral sham stimulation twice daily.

Contacts

Public
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Eligibility criteria

Inclusion criteria

1. Participants must be 18 years or older.

2. They must be diagnosed with schizophrenia and the diagnosis must be confirmed by a standardised psychiatric assessment, the Schedules for Clinical Assessment in Neuropsychiatry (SCAN 2.1).

3. Patients included must have prominent negative symptoms and patients must have a negative subscore = or > than 15 on the Positive and Negative Syndrome Scale for Schizophrenia (PANSS).

4. Only patients who are fully capable of making their own decision regarding participation in the research will be included.

Exclusion criteria

1. Exclusion criteria include rTMS and MRI contraindications (e.g. a personal or family history of epileptic seizures, history of brain surgery, intracerebral or pacemaker implants, inner ear prosthesis or other metal prosthetics/implants).

2. Neurological disorders, a head injury with loss of consciousness in the past.

3. Substance dependency within the previous 6 months.

4. Previous treatment with rTMS.

5. Severe behavioural disorders.

6. Inability to provide informed consent.

7. Claustrophobia.

8. Female patients who are pregnant will be excluded.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)

Control:	Placebo

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-05-2008
Enrollment:	32
Type:	Anticipated

Ethics review

Positive opinion

Date:	01-03-2008
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL1216
NTR-old	NTR1261
Other	METC : 2008/058
ISRCTN	ISRCTN wordt niet meer aangevraagd

Study results

Summary results
N/A