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Localization of transcranial magnetic stimulation in treatment of depression

Submission date	Recruitment status	[ ] Prospectively registered
26/01/2017	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
11/04/2017	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
27/12/2023	Mental and Behavioural Disorders	[ ] Record updated in last year

Plain English summary of protocol

Background and study aims

Major depressive disorder (MDD) is one of the most common mental health conditions in the world. The symptoms can vary greatly from person to person, but they generally include low mood, problems with sleeping and/or eating, and a general loss of interest in life. Treatment often relies heavily on antidepressant medications, which work by increasing the activity and levels of a group of chemicals in the brain (neurotransmitters) and talking therapy. Repetitive transcranial magnetic stimulation (rTMS) is a relatively new treatment of depression. It involves using magnetic fields to stimulate brain cells in order to improve the symptoms of depression. Studies have shown that this treatment can produce changes in the brain that have been found to be related to mood regulation. This study is looking at the effects of targeting rTMS on a particular area of the brain.

Who can participate?

Patients with MDD aged between 15 and 60 years old.

What does the study involve?

All participants receive transcranial magnetic stimulation (rTMS) as a part of their normal care. During the first and sixth week of their treatment, participants are interviewed and asked to complete a questionnaire in order to assess the severity of their depression symptoms and their functioning, in order to find out whether the rTMS treatment has made any different to their condition.

What are the possible benefits and risks of participating?

There are no direct benefits involved with participating in this study. Strong magnetic fields used in MRI and TMS are a risk for patients with magnetic objects or medical devices in the body and so patients with these are unable to take part. There are no other notable risks involved with participating.

Where is the study run from?

Helsinki University Hospital (Finland)

When is the study starting and how long is it expected to run for?
January 2015 to January 2019

Who is funding the study?
Helsinki University Hospital (Finland)

Who is the main contact?
Dr Tuukka Raij

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

Protocol serial number
05012017

Study information

Scientific Title
Imaging-based optimization of repetitive transcranial magnetic stimulation for depression

Study objectives
Effectiviness of rTMS treatment of depression depends on E-field location in the left dorsolateral cortical region.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Helsinki University Hospital Ethics Committee for gynaecology and obstetrics, pediatrics and psychiatry, 11/06/2015, ref: 215/13/03/03/2015

Study design
Observational cohort study

Primary study design
Observational

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Major depression

Interventions
The brain stimulation treatment and whole-head MRI is part of the normal clinical care of the patients. For the study purposes, location of the stimulating coil is registered to enable computation of stimulation-induced electric fields and to compare the cortical distribution of the fields with treatment response. Patients admitted to the Helsinki University Central Hospital (HUCH) Aurora neuromodulation unit for treatment of MDD with repetitive transcranial magnetic stimulation (rTMS) are first contacted by phone to inquire about their interest in participating in the study. At the first study visit, participants sign informed consent, fill in the patient health questionnaire-9 (phq-9, assessing symptoms of depression), and are evaluated by the study psychiatrist. The evaluation includes the Mini-International Neuropsychiatric Interview (MINI) for diagnostics, Montgomery–Åsberg Depression Rating Scale (MADRS), Social and Occupational Functioning Assessment Scale (SOFAS), and determination of the patient's TMS motor threshold, which is used to customize the rTMS intensity. TMS coil is placed over the EEG electrode location F5 situated over the left dorsolateral prefrontal cortex, and a mark for the coil position is saved in the neuronavigation system. On the subsequent 23 visits, rTMS is applied at the marked position using a TMS neuronavigation system. Exact coil position with respect to the anatomical MRI is recorded during all TMS sessions. TMS is given with a Magstim Rapid stimulator at 110-120% of motor threshold, (4-second trains of 40 pulses at 10 Hz, interleaved with 26-s waiting periods), on 3-5 times days per week at weeks 1-4, on two days at week 5, and once at week 6. At the end of the last rTMS visit at week 6 the participants again fill in the phq-9 and meet the psychiatrist for MADRS and SOFAS assessments. There is no follow-up in the study.

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Transcranial magnetic stimulation

Primary outcome(s)
Depression severity is measured using the Montgomery-Åsberg Depression Rating Scale (MADRS) total at week 1 and 6.

Key secondary outcome(s))
1. Depression severity is measured using The Patient Health Questionnaire (PHQ-9) at week 1 and 6
2. Functioning is measured using Social and Occupational Functioning Assessment Scale (SOFAS) at week 1 and 6

Completion date

31/01/2023

Eligibility

Key inclusion criteria
1. Major depressive disorder in MINI interview
2. Aged 15-60 years

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
15 years

Upper age limit
60 years

Sex
All

Key exclusion criteria
1. Serious psychiatric or somatic illness
2. MRI/TMS contraindications

Date of first enrolment
01/05/2016

Date of final enrolment
31/10/2022

Locations

Countries of recruitment
Finland

Study participating centre
Helsinki University Hospital
Aurora ECT unit
Helsinki
Finland
00029 HUS

Sponsor information

Organisation
Helsinki University Hospital

ROR
https://ror.org/02e8hzf44

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Helsinki University Hospital

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are not expected to be made available to protect patient identity.

IPD sharing plan summary
Not expected to be made available

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