ISRCTN10284151 https://doi.org/10.1186/ISRCTN10284151

Impact of magnetic stimulation on depression and brain health

Submission date
17/02/2025

Recruitment status
No longer recruiting

Registration date
10/03/2025

Overall study status
Completed

Last Edited
10/03/2025

Condition category
Mental and Behavioural Disorders

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Major depressive disorder (MDD) is a severe psychiatric condition affecting millions of people worldwide. Some individuals with MDD do not respond adequately to standard antidepressant treatments, a condition known as treatment-resistant depression (TRD). One promising alternative treatment is repetitive transcranial magnetic stimulation (rTMS), a non-invasive brain stimulation technique. This study aims to assess the impact of rTMS on depressive symptoms, cognitive functions, and blood levels of a protein called brain-derived neurotrophic factor (BDNF), which is involved in brain plasticity, the brain's ability to change its structure and function.

Who can participate?
Adult patients diagnosed with TRD who are aged between 18 and 70 years old

What does the study involve?
Participants are divided into two groups:
rTMS group (13 patients): Receives 20 sessions of rTMS over 4 weeks.
Control group (12 patients): Continue their regular treatment without rTMS.
Both groups undergo clinical and cognitive assessments before and after the treatment period. The researchers will measure depressive symptoms, cognitive functions (e.g., memory, verbal fluency), and blood BDNF levels at two time points.

What are the possible benefits and risks of participating?
Potential benefits: Participants in the rTMS group may experience improvements in mood and cognitive function, contributing to a better quality of life.
Possible risks: rTMS is generally safe but can cause mild side effects such as headaches, scalp discomfort, or temporary fatigue.

Where is the study run from?
The University of Cagliari and Studio Corona, within a specialized outpatient psychiatric clinic.

When is the study starting and how long is it expected to run for?
March 2018 to December 2024

Who is funding the study?
Section of Psychiatry, Department of Medical Sciences and Public Health, University of Cagliari (internal funding)

Who is the main contact?
Prof. Mirko Manchia, mirko.manchia@unica.it

Contact information

Type(s)
Public, Scientific

Contact name
Mr Enrico Ginelli

ORCID ID
https://orcid.org/0009-0009-6782-9474

Contact details
Via Michelangelo N°30
Capoterra
Italy
09012
+39 3474056086
enrico.ginelli@unica.it

Type(s)
Principal investigator

Contact name
Dr Lucia Sanna

Contact details
-
Cagliari
Italy
09124
+39 3452578493
luc.sanna1@studenti.unica.it

Additional identifiers

Study information

Scientific Title
Impact of repetitive transcranial magnetic stimulation on clinical and cognitive outcomes, and brain-derived neurotrophic factor (BDNF) levels in treatment-resistant depression

Acronym

rTMS-TRD

Study objectives
Our main hypothesis is that rTMS reduces depressive symptoms, improves cognitive performance, and raises BDNF levels, in our sample of treatment-resistant depression patients.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 28/03/2018, Comitato Etico Indipendente (Independent Ethical Committee) (Azienda Ospedaliero Universitaria - P.O. San Giovanni di Dio - via Ospedale 54, Cagliari, 09124, Italy; +39 0706092547; sperimentazioni.cliniche@aoucagliari.it), ref: NP/2018/1647

Study design
Single-center observational within-subject study

Primary study design
Observational

Study type(s)
Treatment, Efficacy

Health condition(s) or problem(s) studied
Treatment-resistant depression

Interventions
This is a single-center, observational, within-subject study designed to evaluate the effects of repetitive transcranial magnetic stimulation (rTMS) on treatment-resistant depression (TRD). The study includes 25 patients diagnosed with TRD, all undergoing a total of 20 rTMS sessions over four weeks. Clinical, cognitive, and biological assessments are conducted at baseline (T0) and post-treatment (T1) to measure changes in depressive symptoms (HAMD, CGI), cognitive function (MMSE, Digit Span, Verbal Fluency), and BDNF blood levels.

Intervention Type
Procedure/Surgery

Primary outcome(s)
Depressive symptoms measured using the Hamilton Depression Rating Scale (HAM-D) at baseline and 4 weeks

Key secondary outcome(s))
The following secondary outcome measures are assessed at baseline and 4 weeks:
1. Serum BDNF levels measured using a Human-BDNF ELISA kit
2. Cognitive performance measured using a series of cognitive tests: Mini-Mental State Examination (MMSE), Trail-Making Test (TMT), Digit Span Test (DST), and Verbal Fluency Test

Completion date
31/12/2024

Eligibility

Key inclusion criteria
1. Aged 18-70 years
2. DSM-5 MDD diagnosis with treatment resistance (TRD) (≥2 failed antidepressants)
3. Available for full rTMS treatment and assessments
4. Signed informed consent

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 years

Upper age limit
70 years

Sex
All

Total final enrolment
25

Key exclusion criteria
1. Psychiatric comorbidities (bipolar, schizophrenia, active substance use disorder)
2. Neurological conditions (epilepsy, stroke, TBI, neurodegenerative diseases)
3. Metal implants (pacemaker, neurostimulator, cochlear implants)
4. Severe cognitive impairment (low MMSE score)
5. Pregnancy/lactation
6. Recent medication changes (<4 weeks)
7. Participation in another clinical trial

Date of first enrolment
28/03/2018

Date of final enrolment
30/06/2018

Locations

Countries of recruitment
Italy

Study participating centre
Studio Corona
Via Tolmino, 25
Cagliari
Italy
09122

Sponsor information

Organisation
Azienda Ospedaliero-Universitaria Cagliari

ROR
https://ror.org/034qxt397

Funder(s)

Funder type
University/education

Funder Name
University of Cagliari

Alternative Name(s)
Università degli Studi di Cagliari, Università di Cagliari, UNICA

Funding Body Type
Government organisation

Funding Body Subtype
Universities (academic only)

Location
Italy

Results and Publications

Individual participant data (IPD) sharing plan
The dataset generated will be published as a supplement to the results publication.

IPD sharing plan summary