

Impact of magnetic stimulation on depression and brain health

Submission date 17/02/2025	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 10/03/2025	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 10/03/2025	Condition category Mental and Behavioural Disorders	<input type="checkbox"/> Individual participant data
		<input checked="" type="checkbox"/> 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

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Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

Nil known

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

Secondary study design

Cohort study

Study setting(s)

Hospital, Laboratory, University/medical school/dental school

Study type(s)

Treatment, Efficacy

Participant information sheet

No participant information sheet available

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 measure

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

Secondary outcome measures

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

Overall study start date

28/03/2018

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

Age group

Mixed

Lower age limit

18 Years

Upper age limit

70 Years

Sex

Both

Target number of participants

50

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

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Sponsor type

University/education

Website

<http://www.unica.it/>

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

Publication and dissemination plan

Planned publication in peer-reviewed journal.

Intention to publish date

01/03/2025

Individual participant data (IPD) sharing plan

The dataset generated will be published as a supplement to the results publication.

IPD sharing plan summary

Published as a supplement to the results publication