ISRCTN70121208 https://doi.org/10.1186/ISRCTN70121208

Clinical effectiveness of repetitve transcranial magnetic stimulation (rTMS) as an adjunctive therapy in depression - a catchment area-based randomised controlled trial

Submission date
07/02/2007

Recruitment status
No longer recruiting

Registration date
05/03/2007

Overall study status
Completed

Last Edited
03/05/2011

Condition category
Mental and Behavioural Disorders

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Declan McLoughlin

Contact details
Section of Old Age Psychiatry PO70
Institute of Psychiatry
De Crespigny Park
London
United Kingdom
SE5 8AF
+44 (0)20 78480547
d.mcloughlin@iop.kcl.ac.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title

Acronym
TMSplus Trial

Study objectives
TMS can be used as an adjunctive treatment for depression

Ethics approval required
Old ethics approval format

Ethics approval(s)
Institute of Psychiatry Ethical Committee (Research), ref: 251/00

Study design
Parallel group randomised placebo-controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Major depressive disorder

Interventions
Real or sham repetitve transcranial magnetic stimulation (rTMS)

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Hamilton Rating Scale for Depression (HDRS)

Secondary outcome measures
Clinical:
1. Beck Depression Inventory-II (BDI-II)
2. Visual Analogue Mood Scales (VAMS)
3. Brief Psychiatric Rating Scale (BPRS)

Subjective side-effects:
1. Modified Columbia ECT Subjective Side Effects Schedule (CSSES)

Cognition:
1. CAMCOG, digit-span test
2. Digit symbols modalities test
3. Grooved pegboard test

Quality of life:
SF-36 questionnaire

Economic:
Client Service Receipt Inventory (CSRI)

Overall study start date
01/03/2002

Completion date
31/12/2005

Eligibility

Key inclusion criteria
Over 18 years old, right-handed and have a diagnosis of major depressive disorder (DSM-IV)

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Not Specified

Target number of participants
54

Key exclusion criteria

1. History of seizures
2. Head injury with loss of consciousness
3. Brain surgery
4. Presence of metallic implants
5. Evidence of dementia or other Axis 1 diagnosis
6. Substance misuse within the previous six months
7. Previous treatment with rTMS
8. Inability to provide informed consent

Date of first enrolment
01/03/2002

Date of final enrolment
31/12/2005

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Section of Old Age Psychiatry PO70
London
United Kingdom
SE5 8AF

Sponsor information

Organisation
South London and Maudsley NHS Trust (UK)

Sponsor details
Denmark Hill
London
SE5 8AZ
London
England
United Kingdom
SE5 8AZ

Sponsor type
Hospital/treatment centre

Website

http://www.slam.nhs.uk/

ROR
https://ror.org/015803449

Funder(s)

Funder type
Charity

Funder Name
Guy's & St Thomas' Charitable Foundation (R001126) (UK)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

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?
Results article	results	01/03/2008		Yes	No