ISRCTN03884521 https://doi.org/10.1186/ISRCTN03884521

Theta Burst Stimulation for motor impairment after stroke

Submission date	Recruitment status	[_] Prospectively registered
29/04/2010	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
29/04/2010	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
26/07/2013	Circulatory System	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
3279; G0401353

Study information

Scientific Title
Enhancing the effect of physical therapy for motor impairment after stroke with Theta Burst Stimulation

Acronym
TBS Study

Study objectives
In this study we plan to investigate whether brain stimulation can be used as an add-on treatment to consolidate the benefit from patterned upper limb physiotherapy and induce further hand motor improvement in chronic stroke patients.

To stimulate the brain we plan to use Theta Burst Stimulation (TBS), a novel paradigm of repetitive transcranial magnetic stimulation (TMS), aiming to increase cortical excitability of the affected (ipsilesional) hemisphere.

According to evidence so far, we believe that increased ipsilesional excitability can be achieved by:
1. Direct facilitation of the affected hemisphere (ipsilesional facilitation)
2. Inhibition of the unaffected hemisphere (contralesional inhibition)

Primary aim:
To investigate whether daily treatment with TBS followed by patterned physical therapy for a period of two weeks can lead to significant and sustained improvement of hand motor behavior in chronic stroke patients.

Secondary aims:
1. To study the physiological correlates of the potential behavioral gains
2. To identify physiological predictors of likelihood of response to the proposed intervention, so that appropriate patients may be targeted in future trials

Physiological correlates will be studied using TMS and functional magentic resonance imaging (fMRI) as detailed below.

Ethics approval required
Old ethics approval format

Ethics approval(s)
NHNN and ION Joint Research Ethics Committee approved on the 25/02/2005 (ref: 04/Q0512 /108)

Study design
Randomised interventional treatment trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)

Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Topic: Stroke Research Network; Subtopic: Rehabilitation; Disease: Therapy type

Interventions
Physical therapy (physiotherapy):
The protocol for physical therapy has been developed in collaboration with the therapy services department at the National Hospital for Neurology and Neurosurgery. It expands upon previous protocols by ensuring the equivalence of task intensity, repetition rate and verbal feedback across subjects. Treatment will be task oriented and individualised based on the findings of a questionnaire about current functional difficulties and an objective examination.

Theta Burst Stimulation:
TMS is a well tolerated method of stimulating the human cortex through the intact scalp. We will employ a new pattern of repetitive TMS called Theta Burst Stimulation (TBS). Each burst consists of 3 low intensity (80% aMT, see further on) stimuli, repeating at high frequency (50Hz). Bursts are repeating at 5Hz, i.e. the "theta" rhythm of the EEG. A total of 15 pulses are delivered per second. TBS effect on corticospinal excitability can be either inhibitory of facilitatory, depending on the pattern.

Follow up length: 3 months
Study entry: single randomisation only

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Action Research Arm Test, measured at initial assessment, 2 day post-intervention follow-up, 1 month follow-up and 3 month follow-up.

Secondary outcome measures
1. Electrophysiological measures of corticospinal excitability, intracortical interactions and interhemispheric balance, measured at initial assessment, 2 day post-intervention follow-up, 1 month follow-up and 3 month follow-up
2. Functional Magnetic Resonance Imaging: Measurement of motor and sensory related brain activation only performed at initial and two day post intervention follow-up

Overall study start date
01/11/2005

Completion date
31/12/2010

Eligibility

Key inclusion criteria
1. History of a single ischaemic stroke, initially affecting the hand
2. Minimum interval since stroke onset one year (no upper limit)
3. Residual impairments of hand function (strength and/or dexterity)
4. Some degree of hand movement defined as present wrist extension (>=20%) and ability to grasp
5. Capable of giving informed consent
6. Aged 18 - 80 years, either sex

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 45

Key exclusion criteria
1. Intracerebral hemorrhage
2. Large ischaemic lesions involving almost the whole MCA territory
3. Significant tone problems in the hand (greater than 2 in the Ashworth Scale)
4. Severe cognitive impairment defined as mini-mental state examination (MMSE) less than 20
5. Residual aphasia or visual field defect (greater than or equal to 2 in the relative item of the National Institutes of Health Stroke Scale [NIHSS])
6. Past or current history of other neurological or psychiatric disease including epilepsy, previous or recurrent stroke and peripheral neuropathy
7. Major systemic illness
8. Use of anticonvulsant, psychotropic or sedative or medication
9. Excessive use of alcohol or other substances
10. Accepted contraindications for TMS (presence of metal in the head (excluding the mouth), intracardiac lines, cardiac pacemakers)

Date of first enrolment
01/11/2005

Date of final enrolment
31/12/2010

Locations

Countries of recruitment
England

Italy

United Kingdom

Study participating centre
Institute of Neurology
London
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Sponsor information

Organisation
University College London Hospitals NHS Foundation Trust (UK)

Sponsor details
Joint UCLH/UCL Biomedical Research Unit
1st Floor Maple House
149 Tottenham Court Road
London
England
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W1P 9LL

Sponsor type
Hospital/treatment centre

Website
http://www.uclh.nhs.uk/

ROR
https://ror.org/042fqyp44

Funder(s)

Funder type
Research council

Funder Name
Medical Research Council (MRC) (UK) (ref: G0401353)

Alternative Name(s)
Medical Research Council (United Kingdom), UK Medical Research Council, MRC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

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	01/10/2012		Yes	No