Can Theta Burst stimulation accelerate relearning of impaired wrist and hand movements early after stroke?

Submission date	Recruitment status	[_] Prospective	
18/06/2010	No longer recruiting	[] Protocol	
Registration date	Overall study status	[] Statistical a	
18/06/2010	Completed	[X] Results	
Last Edited	Condition category	[] Individual p	
06/12/2013	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 4528

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Study information

Scientific Title

A multicentre randomised interventional treatment trial of theta burst stimulation to accelerate re-learning of impaired wrist and hand movements early after stroke

Acronym

TBS3 study

Study objectives

26 patients with a first-ever motor stroke initially affecting the hand will be recruited from 5 sites: the National Hospital for Neurology and Neurosurgery, the Homerton, the Whittington, St Georges and St Marys Hospitals.

We will invite patients who are still having mild to moderate problems with their hand function 1 - 3 months after the stroke. Potential participants will be approached and informed about the study by the member of the research team responsible for their care. All research procedures will take place at the Institute of Neurology.

Ethics approval required

Old ethics approval format

Ethics approval(s)

The National Hospital of Neurology and Neurosurgery and Institute of Neurology Joint Research Ethics Committee approved on the 1st November 2007 (ref: 07/H0715/94)

Study design Multicentre 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: Device used, Therapy type

Interventions

Motor training:

We will study how patients can learn to improve their performance in three different movements that are important for fine hand function: wrist extension (needed for grasping and releasing), precision grip and thumb opposition (both needed for grasping and manipulation). The training involves repetitions of the respective movement in 10 blocks of 15 trials, separated by 1 minute periods of rest. In this way, the total amount of training for each movement will be around 15 minutes.

Theta Burst Stimulation:

Theta Burst Stimulation (TBS)(Huang 2005) is a form of RTMS: very short bursts of stimuli (3 pulses at 50 Hz) are repeated five times every second using low intensity stimulation (80% of active motor threshold). In normal subjects, when TBS is applied in a specific excitatory pattern, termed iTBS, over the hand motor area excitability is enhanced for up to 1 hour. We have shown that iTBS can increase the excitability of the stroke side in chronic stroke patients in a similar way.

Control Group:

The control group performs the same exercise regime but receives sham transcranial magnetic stimulation (TMS).

Participation in each arm of the trial is one week. Study entry: single randomisation only

Intervention Type

Other

Phase Phase II

Primary outcome measure

Motor performance, collected during each practice

Secondary outcome measures

Standardised tests of the arm and hand function that have been used repeatedly to assess recovery, performed on day 1 and 5:

- 1. Action Research Arm Test (ARAT)
- 2. Jebsen Taylor Hand Test
- 3. 9-Hole Peg Test
- 4. Electrophysiological measures of corticospinal excitability determined by TMS

Overall study start date

01/01/2008

Completion date 31/12/2010

Eligibility

Key inclusion criteria

- 1. First ever ischaemic stroke (previous transient ischaemic attack [TIA] is not a problem)
- 2. One to three months post stroke

3. Some movement in the wrist and fingers (wrist extension greater than or equal to 20° and thumb flexion greater than or equal to 10°)
4. English speaking

5. Aged over 18 years of age, either sex

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

Planned sample size: 30; UK sample size: 26

Key exclusion criteria

1. Intracerebral or subarachnoid haemorrhage

2. Large strokes (greater than 50% of the middle cerebral artery [MCA] territory)

3. Increased muscular tone (greater than 2 in the Ashworth scale or not able to let go after grip without using the intact hand)

4. Cardiac pacemaker or intracardiac lines

5. Metallic objects in the head or in the eyes (e.g. clips from surgery, exposure to fast metallic flakes; metal in the mouth/teeth is not a problem)

6. Any history of epilepsy or fits including childhood

7. Inability to consent or comply with the study procedures (cognitive impairment, significant aphasia, visual field defect, or non-English speakers)

Date of first enrolment

01/01/2008

Date of final enrolment 31/12/2010

Locations

Countries of recruitment England

United Kingdom

Study participating centre

Institute of Neurology London United Kingdom WC1N 3BG

Sponsor information

Organisation University College London Hospitals NHS Foundation Trust (UK)

Sponsor details 250 Euston Road London England United Kingdom NW1 2PG

Sponsor type Hospital/treatment centre

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

ROR https://ror.org/042fqyp44

Funder(s)

Funder type Research organisation

Funder Name The Stroke Association (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	01/10/2012		Yes	No