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Can Theta Burst stimulation accelerate re-learning of impaired wrist and hand movements early after stroke?

Submission date 18/06/2010	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 18/06/2010	**Overall study status** Completed	
Last Edited 06/12/2013	**Condition category** 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

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