

# Theta Burst Stimulation for motor impairment after stroke

<b>Submission date</b> 29/04/2010	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 29/04/2010	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 26/07/2013	<b>Condition category</b> Circulatory System	<input type="checkbox"/> Individual participant data

**Plain English summary of protocol**  
Not provided at time of registration

## Contact information

**Type(s)**  
Scientific

**Contact name**  
Ms Ulrike Hammerbeck

**Contact details**  
Institute of Neurology  
Queen Square London  
Queen Square  
London  
United Kingdom  
WC1N 3BG

## 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 magnetic 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 or 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 ( $\geq 20\%$ ) 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

United Kingdom

WC1N 3BG

# 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

United Kingdom

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?
<a href="#">Results article</a>	results	01/10/2012		Yes	No