

Neural correlates of cognitive motor interference (CMI) while walking

Submission date 17/11/2008	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 27/11/2008	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 06/06/2016	Condition category Circulatory System	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

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
TSA 2007/09

Study information

Scientific Title

Cortical activation of cognitive motor interference while walking: a near-infrared spectroscopic study

Acronym

CMI

Study objectives

1. There may be a relationship between the degree of regional brain activation and/or the temporal activation pattern and performance in cognitive and motor tasks under dual task conditions
2. This relationship may be different following a stroke than in healthy controls

Ethics approval required

Old ethics approval format

Ethics approval(s)

Oxfordshire Research Ethics Committee C, 24/07/2008, ref: 08/H0606/55

Study design

Observational cross-sectional study

Primary study design

Observational

Secondary study design

Cross sectional study

Study setting(s)

Hospital

Study type(s)

Diagnostic

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

Stroke

Interventions

Baseline assessments include:

1. The Mini Mental State Examination: the MMSE is a brief screening tool to provide quantitative assessment of cognitive function. It consists of 11 simple questions or tasks. Typically, they are grouped into seven domains; orientation to time, orientation to place, registration of three words, attention and calculation.
2. Edinburgh Handedness Inventory: this is a brief questionnaire of 10 short items, which determines subject's hand dominance.
3. Barthel Index: a simple index of independence in activities of daily living (ADL). It consists of 10 common ADL activities, which they are assessed for independence/dependence.

4. Modified Physical Activity Scale for the elderly: a self reported physical activity questionnaire that covers one week.
5. Berg Balance Scale (BBS): the BBS provides a quantitative assessment of balance. It consists of 14 items requiring subjects to maintain or complete movement tasks of varying levels of difficulty. All items are common to everyday life.

The results of the assessments above will be reported together with the primary/secondary outcomes, as they might correlate with differences in CMI.

Brain activation in both stroke and control subjects will be examined by near-infrared spectroscopy (NIRS) alongside behavioural performance of walking and cognitive tasks (calculation). The participants will be asked to perform the concurrent tasks when seated and walking. Gait parameters will be measured using a well-validated gait analysis system (Xsens, The Netherlands).

Intervention Type

Other

Phase

Not Applicable

Primary outcome measure

Task-related changes in oxygenated and deoxygenated haemoglobins in the frontal lobe as measured by NIRS.

Secondary outcome measures

1. Rate of backward calculation (number per minute)
2. Number of errors in backward calculation (errors per trial)
3. Spatiotemporal gait measures (speed, cadence, step time, stride time, step length, stride length, step width)

Overall study start date

01/07/2008

Completion date

01/07/2010

Eligibility

Key inclusion criteria

Patients will be selected from those treated in the Oxford Radcliffe Hospitals who are:

1. More than 6 months following a first stroke
2. Both males and females, aged 45 to 80 years
3. With an ischaemic infarct upon computed tomography (CT) or magnetic resonance imaging (MRI) scan
3. Able to perform a simple reciprocal bilateral foot tapping task, walk safely on a treadmill with or without mobility aids
4. Be able to give informed consent

Sex and age-matched controls will be chosen who do not have a known neurological disease, a history of hypertension, cardiac disease or diabetes.

Participant type(s)

Patient

Age group

Adult

Sex

Both

Target number of participants

36

Key exclusion criteria

1. Dementia
2. Aphasia significantly limiting communication
3. History of previous symptomatic strokes or neurological disease
4. Known psychiatric disease or claustrophobia, or other conditions precluding safe MRI (e.g., pacemaker or other metal implant)

Date of first enrolment

01/07/2008

Date of final enrolment

01/07/2010

Locations**Countries of recruitment**

England

United Kingdom

Study participating centre

Oxford Brookes University

Oxford

United Kingdom

OX3 0BP

Sponsor information**Organisation**

Oxford Brookes University (UK)

Sponsor details

c/o Prof Linda King
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Sponsor type

University/education

Website

<http://www.brookes.ac.uk>

ROR

<https://ror.org/04v2twj65>

Funder(s)

Funder type

Charity

Funder Name

Stroke Association (ref: TSA 2007/09)

Alternative Name(s)**Funding Body Type**

Private sector organisation

Funding Body Subtype

Associations and societies (private and public)

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