ISRCTN59902842 https://doi.org/10.1186/ISRCTN59902842

Neural correlates of cognitive motor interference (CMI) while walking

Submission date 17/11/2008	**Recruitment status** No longer recruiting	[ ] Prospectively registered [ ] Protocol [ ] Statistical analysis plan [ ] Results [ ] Individual participant data [ ] Record updated in last year
Registration date 27/11/2008	**Overall study status** Completed	
Last Edited 06/06/2016	**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
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

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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