ISRCTN84669284 https://doi.org/10.1186/ISRCTN84669284

Non-invasive measurement of cerebral energy status: an opportunity to target neuroprotection in brain injury

Submission date	Recruitment status
12/05/2010	No longer recruiting
Registration date	**Overall study status**
12/05/2010	Completed
Last Edited	**Condition category**
12/05/2010	Injury, Occupational Diseases, Poisoning

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
5789

Study information

Scientific Title

Acronym
Non-invasive measurement of cerebral energy status

Study objectives
We will use a combination of near infrared spectroscopy systems to assess non-invasively cerebral oxygenation, perfusion and cellular metabolic status in healthy volunteers and critically brain injured adults in order to monitor and quantify cerebral ischaemia in the latter. Specifically we will non-invasively measure changes in cell energy status by monitoring concentration changes in cytochrome oxidase (ox-CCO) using a novel hybrid optical spectroscopy system optimised for the measurement of ox-CCO in adults.

Ethics approval required
Old ethics approval format

Ethics approval(s)
MREC approved (ref: 04/Q0512/67)

Study design
Single centre non-randomised process of care trial

Primary study design
Observational

Secondary study design
Single-centre

Study setting(s)
Other

Study type(s)
Quality of life

Participant information sheet

Health condition(s) or problem(s) studied
Topic: Neurological; Subtopic: Neurological (all Subtopics); Disease: Nervous system disorders

Interventions
Volunteer studies: Hyperoxia, hypoxia, hypercapnea and hypocapnea
Patient studies: NIRS-derived changes in cerebral oxygenation, haemodynamics and oxidised cytochorme c oxidase concentrations, and cerebral microdialysis-derived markers of ischaemia (lactate:pyruvate ratio and glucose).

Study entry: registration only

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Infrared specotrscopy

Secondary outcome measures
Estimated cerebal oxygen delivery

Overall study start date
01/01/2006

Completion date
31/12/2011

Eligibility

Key inclusion criteria
1. Healthy volunteers and patients with severe traumatic brain injury
2. Male and female, lower age limit of 18 years

Participant type(s)
Healthy volunteer

Age group
Adult

Lower age limit
18 Years

Sex
Not Specified

Target number of participants
Planned sample size: 170

Key exclusion criteria
Not provided at time of registration

Date of first enrolment
01/01/2006

Date of final enrolment
31/12/2011

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
National Hospital for Neurology & Neurosurgery
London
United Kingdom
WC1N 3BG

Sponsor information

Organisation
University College London Hospitals NHS Foundation Trust (UK)

Sponsor details
Research and Development Directorate
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 council

Funder Name
Engineering and Physical Sciences Research Council (EPSRC) (UK)

Alternative Name(s)

UKRI Engineering and Physical Sciences Research Council, Engineering and Physical Sciences Research Council - UKRI, Engineering & Physical Sciences Research Council, EPSRC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Funder Name
Medical Research Council (MRC) (UK)

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?
Results article	results	01/03/2008		Yes	No