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

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

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

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Additional identifiers

Protocol serial number
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

Study type(s)
Quality of life

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(s)
Infrared specotrscopy

Key secondary outcome(s))
Estimated cerebal oxygen delivery

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

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex

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
United Kingdom

England

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

Sponsor information

Organisation

University College London Hospitals NHS Foundation Trust (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, Science Research Council, Science and Engineering Research Council, EPSRC, SRC, SERC

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, Medical Research Committee and Advisory Council, MRC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/03/2008		Yes	No