ISRCTN19146279 https://doi.org/10.1186/ISRCTN19146279

Cerebral metabolic effects of strict normoglycaemia versus current clinical glycaemic control following severe traumatic brain injury

Submission date
28/09/2007

Recruitment status
No longer recruiting

Registration date
28/09/2007

Overall study status
Completed

Last Edited
29/01/2018

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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N0544183600

Study information

Scientific Title
Cerebral metabolic effects of strict normoglycaemia versus current clinical glycaemic control following severe traumatic brain injury

Study objectives
This study aims to establish whether strict control of blood glucose, which has many benefits for critically ill, can be safely applied to patients with brain trauma without causing negative influence on brain glucose levels and energy state. This will be done by comparing the effects of strict glucose control and current 'loose' control on brain chemistry and energy production.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Cambridgeshire 2 Research Ethics Committee, 25/08/2006, ref: 06/Q0108/215

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
PIS at: http://www.medschl.cam.ac.uk/anaesthetics/wp-content/uploads/2010/02/Blood-sugar-consultee-information-sheet-150310.pdf

Health condition(s) or problem(s) studied
Injury, Occupational Diseases, Poisoning: Traumatic brain injury

Interventions
High blood sugar (glucose) levels are common during critical illness and are strongly linked to poor outcome. Large scale study has now demonstrated that strict control of blood glucose with insulin can reduce the risk of death and complications and improve recovery in surgical intensive care patients. However, after head injury glucose is the most important nutrient required by the brain. The energy demands of the injured brain are higher than those in the normal brain and strictly normal blood glucose levels acceptable for general intensive care patients may be too low for a patient with severe head injury. If injured brain does not receive enough glucose its energy production could deteriorate which may put brain at risk of further injury or delayed recovery. This study aims to establish whether strict control of blood glucose, which has many

benefits for the critically ill, can be safely applied to patients with brain trauma without causing negative influences on brain. This will be done by comparing the effects of strict glucose control and current loose control on brain chemistry and energy production, assessed using monitoring devices, all of which are in the routine clinical use.
The study will be performed prospectively and will involve 30 patients.
Patients will be randomly (by chance) divided into two groups.
In the first group of patients strict maintenance of normal blood sugar will continue for the first 24 hours and then the current protocol ('loose control') will be used for the following 24 hours.
In the second group of patients the order of the treatment protocols will be reverse (ie initial 24 hours of current 'loose' control will be followed by 24 hours of strict normoglycaemia). The whole duration of the study for the individual patient will be 48 hours. Monitoring parameters, that represent brain metabolism and which are routinely captured at the bedside will be used to compare the effects of two blood sugar control protocols. Appropriate statistical methods will be applied to detect significant differences.
If there is no difference in brain monitoring parameters between strict normoglycaemia and current protocols the former will be considered to be safe to use in patients with head injury and will replace our current protocol for glucose control. However, if the study demonstrates that strict normoglycaemia has an adverse effect on brain metabolism it will be avoided in future in patients with head injury and current ('loose control') protocol will continue to be used.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
1. Differences in cerebral monitoring parameters between current 'loose' and intensive glycaemic control periods. Parameters used for comparison will include, cerebral extracellular glucose, lactate, pyruvate, lactate to pyruvate ratio (LP), glutamate and glycerol; brain tissue oxygen (PbO2) and intracranial pressure
2. Glucose levels in each protocol group and the frequency of episodes of hypoglycaemia and hyperglycaemia

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/08/2006

Completion date
01/08/2011

Eligibility

Key inclusion criteria
1. Traumatic brain injury requiring intensive care management with intracranial pressure monitoring
2. Age = 16 years old
3. Absence of exclusion criteria

Participant type(s)
Patient

Age group
Child

Upper age limit
16 Years

Sex
Not Specified

Target number of participants
30

Key exclusion criteria
1. Insulin Dependent Diabetes Mellitus
2. Life threatening injury (not expected to survive > 48 hrs)
3. Pregnancy

Date of first enrolment
01/08/2006

Date of final enrolment
01/08/2011

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Addenbrooke's Hospital
Cambridge
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CB2 2QQ

Sponsor information

Organisation
Record Provided by the NHSTCT Register - 2007 Update - Department of Health

Sponsor details

The Department of Health
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Sponsor type
Government

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Funder(s)

Funder type
Government

Funder Name
Cambridge Consortium - Addenbrooke's (UK), Own Account NHS R&D Support Funding

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	25/01/2018		Yes	No