

The effect of transfusion on cerebral oxygenation in traumatic brain injury

Submission date
08/09/2005

Recruitment status
No longer recruiting

☐ Prospectively registered

☐ Protocol

Registration date
06/10/2005

Overall study status
Completed

☐ Statistical analysis plan

☒ Results

Last Edited
03/03/2009

Condition category
Injury, Occupational Diseases, Poisoning

☐ 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
LREC 02/191

Study information

Scientific Title
The effect of transfusion on cerebral oxygenation in traumatic brain injury: a randomised controlled trial

Study objectives

Blood transfusion does not affect brain oxygenation in traumatic brain injury.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Primary study design

Interventional

Study design

Randomised controlled trial

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Traumatic brain injury

Interventions

Blood transfusion - the patients are randomised to 3 different transfusion triggers

Intervention Type

Other

Phase

Not Applicable

Primary outcome(s)

Brain tissue oxygen partial pressure.

Key secondary outcome(s)

1. Jugular venous saturation
2. Lactate/pyruvate ratio
3. Neurological outcome
4. Cerebral haemodynamics

Completion date

01/12/2005

Eligibility

Key inclusion criteria

1. Greater than 16 years of age
2. Severe traumatic brain injury (i.e. traumatic brain injury resulting in a resuscitated Glasgow coma score of less than or equal to 8, resulting in intracranial hypertension (greater than 20 mmHg for greater than 10 minutes), or requiring neurosurgical intervention
3. Informed assent from the next of kin

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

All

Key exclusion criteria

1. Active haemorrhage
2. Active coronary ischaemia as judged by dynamic electrocardiogram (ECG) changes or positive troponin levels not due to myocardial contusion
3. Inability to place cerebral oxygenation monitors
4. Failure to fall below allocated transfusion threshold during intracranial pressure (ICP) monitoring

Date of first enrolment

01/07/2002

Date of final enrolment

01/12/2005

Locations**Countries of recruitment**

United Kingdom

England

Study participating centre

Department of Anaesthesia

Cambridge

United Kingdom

CB2 2QQ

Sponsor information**Organisation**

Cambridge University Hospitals NHS Foundation Trust (UK)

ROR

<https://ror.org/04v54gj93>

Funder(s)

Funder type

Research organisation

Funder Name

Association of Anaesthetists of Great Britain and Ireland (UK)

Funder Name

Intensive Care Society (UK)

Alternative Name(s)

The Intensive Care Society, ICS

Funding Body Type

Private sector organisation

Funding Body Subtype

Trusts, charities, foundations (both public and private)

Location

United Kingdom

Funder Name

Codman (Johnson & Johnson) (UK)

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	01/03/2009		Yes	No