## The effect of transfusion on cerebral oxygenation in traumatic brain injury

Submission date	Recruitment status  No longer recruiting	Prospectively registered	
08/09/2005		☐ Protocol	
<b>Registration date</b> 06/10/2005	Overall study status Completed	Statistical analysis plan	
		[X] Results	
Last Edited	Condition category	Individual participant data	
03/03/2009	Injury, Occupational Diseases, Poisoning		

#### Plain English summary of protocol

Not provided at time of registration

#### Contact information

#### Type(s)

Scientific

#### Contact name

Prof Arun Gupta

#### Contact details

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#### Additional identifiers

**EudraCT/CTIS** number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers 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

#### 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

#### 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 measure

Brain tissue oxygen partial pressure.

#### Secondary outcome measures

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

#### Overall study start date

01/07/2002

#### 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** 

#### Age group

Adult

#### Sex

Both

#### Target number of participants

30

#### 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

England

United Kingdom

# Study participating centre Department of Anaesthesia Cambridge United Kingdom CB2 2QQ

## Sponsor information

#### Organisation

Cambridge University Hospitals NHS Foundation Trust (UK)

#### Sponsor details

Addenbrooke's Hospital Hills Road Cambridge England United Kingdom CB2 2QQ jn254@cam.ac.uk

#### Sponsor type

Hospital/treatment centre

#### Website

http://www.cuh.org.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)

ICS

#### **Funding Body Type**

Private sector organisation

#### **Funding Body Subtype**

Associations and societies (private and public)

#### Location

United Kingdom

#### Funder Name

Codman (Johnson & Johnson) (UK)

### **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	01/03/2009		Yes	No