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A multicentre randomised controlled trial of mild hypothermia for the prevention of intracranial hypertension in acute liver failure

Submission date 29/09/2006	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 29/09/2006	**Overall study status** Completed	
Last Edited 15/03/2017	**Condition category** Digestive System	

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
N0116169596

Study information

Scientific Title

A multicentre randomised controlled trial of mild hypothermia for the prevention of intracranial hypertension in acute liver failure

Study objectives
The aim of this study is to to establish what temperature is of greatest benefit to patients in preventing the development of cerebral oedema (CO).

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Primary study design
Interventional

Study design
Multi-centre randomised controlled trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Digestive System: Acute liver failure (ALF)

Interventions
Randomised controlled trial

Intervention Type
Other

Phase
Not Specified

Primary outcome(s)
Onset of ICH, development of a sustained rise of ICP (>5 minutes of ICP > 25 mmHb)

Key secondary outcome(s)
Not provided at time of registration

Completion date
01/11/2006

Eligibility

Key inclusion criteria
Not provided at time of registration

Participant type(s)

Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
Not Specified

Key exclusion criteria
Not provided at time of registration

Date of first enrolment
01/05/2005

Date of final enrolment
01/11/2006

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
King's College Hospital
London
United Kingdom
SE5 9RS

Sponsor information

Organisation
Record Provided by the NHSTCT Register - 2006 Update - Department of Health (UK)

Funder(s)

Funder type
Government

Funder Name
Kings College Hospital NHS Trust R&D Consortium

Funder Name
Own Account

Funder Name
NHS R&D Support Funding

Results and Publications

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	01/08/2016		Yes	No