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Surgical Trial In Traumatic intraCerebral Haemorrhage

Submission date	Recruitment status	[X] Prospectively registered
19/03/2009	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
27/03/2009	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
09/09/2015	Injury, Occupational Diseases, Poisoning	

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
HTA 07/37/16; 1.0

Study information

Scientific Title
Surgical Trial In Traumatic intraCerebral Haemorrhage: an international multi-centre pragmatic randomised parallel group trial

Acronym
STITCH (Trauma)

Study objectives
A policy of early surgery in patients with traumatic intracerebral haemorrhage will improve outcome at six months compared to a policy of initial conservative treatment.

More details can be found at: http://www.nets.nihr.ac.uk/projects/hta/073716

As of 27/03/2009, the list of countries is not yet finalised. Other countries from Africa, Asia, Australasia, Europe, and North and South America are planned to be included.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Submission pending as of 19/03/2009

Study design
International multi-centre pragmatic randomised parallel-group trial

Primary study design
Interventional

Secondary study design
Randomised parallel trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Traumatic intracerebral haemorrhage and contusion

Interventions
Early surgery vs initial conservative treatment

Intervention Type

Procedure/Surgery

Primary outcome measure
Unfavourable outcome will be death or severe disability which will be defined using a prognosis based 8 point Glasgow Outcome Scale.

Total duration of follow-up: 6 months

Secondary outcome measures
The following will be assessed at 6 and 12 months:
1. Rankin scale
2. Euroqol EQ-5D
3. Mortality
4. Survival
5. Major Adverse Events (death, pulmonary embolism or deep vein thrombosis, infection, rehaemorrhage)
6. Quality-adjusted life-years (QALYs)
7. Total health care costs
8. Social costs

Overall study start date
01/09/2009

Completion date
28/02/2014

Eligibility

Key inclusion criteria
1. Both males and females, adults aged 14 or over
2. Evidence of a traumatic intracerebral haemorrhage (TICH) on computed tomography (CT) with a single volume of attenuation significantly raised above that of the background white and grey matter that is in total greater than 10 ml calculated by width times height times length in cm divided by 2
3. Within 24 hours of head injury
4. Clinical equipoise: only patients for whom the responsible neurosurgeon is uncertain about the benefits of either treatment are eligible

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
840

Key exclusion criteria
1. A significant surface haematoma (epidural haematoma [EDH] or subdural haematoma [SDH]) requiring surgery (The indications for intervention for these patients are already very well defined)
2. More than two separate haematomas fulfilling inclusion criteria
3. If surgery can not be performed within 36 hours of injury or 12 hours of randomisation (whichever is the shorter)
4. Severe pre-existing physical or mental disability or severe co-morbidity which might lead to a poor outcome even if the patient made a full recovery from the head injury (Examples would be a high level of dependence before the injury or severe irreversible associated injury such as complete spinal cord injury)
5. Permanent residence outside a study country preventing follow up
6. Patient and/or relative has a strong preference for one treatment modality

Date of first enrolment
01/09/2009

Date of final enrolment
28/02/2014

Locations

Countries of recruitment
Czech Republic

Egypt

England

Germany

Greece

India

Italy

Latvia

Lithuania

North Macedonia

Poland

Russian Federation

Spain

United Kingdom

United States of America

Study participating centre
Newcastle University
Newcastle upon Tyne
United Kingdom
NE2 4AE

Sponsor information

Organisation
Newcastle upon Tyne Hospitals NHS Foundation Trust (UK)

Sponsor details
Joint Research Office
R&D Department
4th Floor, Leazes Wing
Royal Victoria Infirmary
Queen Victoria Road
Newcastle upon Tyne
England
United Kingdom
NE1 4LP
-
amanda.tortice@nuth.nhs.uk

Sponsor type
Hospital/treatment centre

Website
http://www.newcastle-hospitals.org.uk/

ROR
https://ror.org/05p40t847

Funder(s)

Funder type
Government

Funder Name
Health Technology Assessment Programme

Alternative Name(s)
NIHR Health Technology Assessment Programme, HTA

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

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?
Protocol article	protocol	16/10/2012		Yes	No
Results article	results	01/09/2015		Yes	No
Results article	results	01/09/2015		Yes	No