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International Surgical Trial in IntraCerebral Haemorrhage

Submission date	Recruitment status	[_] Prospectively registered
23/10/2000	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
23/10/2000	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
09/07/2014	Nervous System Diseases	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr AD Mendelow

Contact details
Professor & Head of Department of Neurosurgery
Neurosurgical Trials Unit
Newcastle University
3-4 Claremont Terrace
Newcastle upon Tyne
United Kingdom
NE2 4AE

Additional identifiers

Protocol serial number
G9702441

Study information

Scientific Title

Acronym

STICH

Study objectives
To determine whether a policy of early surgical evacuation of a spontaneous supratentorial intracerebral haemorrhage will improve outcome compared to a policy of initial conservative treatment. Predefined subgroup analysis will be used to better define indications for early surgery

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

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Neuroscience, psychiatry

Interventions
Early surgical evacuation/initial conservative treatment

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
Glasgow Outcome Scale (favourable = GR/MD: unfavourable = SD/V/D)/ Rankin & Barthel Scale /Mortality

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

Completion date
28/02/2004

Eligibility

Key inclusion criteria
1. Spontaneous, supratentorial intracerebral haemorrhage within 72 h and uncertainty about surgery

2. Minimum clot diameter of 2 cm on initial Computed Tomography (CT)
3. Glasgow Coma Score of 5 or above

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Not Specified

Sex
All

Key exclusion criteria
1. Haemorrhage due to aneurysm or arteriovenous malformation
2. Cerebellar or brainstem haemorrhages or brainstem extensions of a supratentorial haemorrhage
3. ICH secondary to a tumour or trauma
4. Where surgery cannot be performed within 24 h of randomisation
5. Evidence of severe pre-existing physical or mental disability or of severe co-morbidity which might interfere with the assessment of outcome

Date of first enrolment
28/02/1998

Date of final enrolment
28/02/2004

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Professor & Head of Department of Neurosurgery
Newcastle upon Tyne
United Kingdom
NE2 4AE

Sponsor information

Organisation
Medical Research Council (MRC) (UK)

Funder(s)

Funder type
Research council

Funder Name
Medical Research Council (MRC) (UK)

Alternative Name(s)
Medical Research Council (United Kingdom), UK Medical Research Council, Medical Research Committee and Advisory Council, MRC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

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	01/01/2005		Yes	No
Results article	results	01/01/2006		Yes	No
Results article	results	01/01/2006		Yes	No