International Surgical Trial in IntraCerebral Haemorrhage

Submission date	Recruitment status No longer recruiting	Prospectively registered	
23/10/2000		☐ 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

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Additional identifiers

Protocol serial number G9702441

Study information

Scientific Title

Acronym

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, 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
Participant information sheet	Participant information sheet	11/11/2025 11/11/2025	No	Yes