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Surgical trial in lobar intracerebral haemorrhage

Submission date	Recruitment status	[X] Prospectively registered
31/03/2006	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[X] Statistical analysis plan
11/10/2006	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
10/05/2023	Circulatory System	

Plain English summary of protocol

Background and study aims
STICH II is a study for patients with a type of stroke which causes bleeding into the brain (spontaneous intracerebral haemorrhage) where the bleed is close to the surface of the brain and between 10-100 ml in size. STICH II will examine whether it is better to give these patients an early operation (early surgery) or to monitor them carefully (initial conservative treatment) with an option to operate later on if necessary.

Who can participate?
This study is for adult patients who have had a CT scan confirming that they have a bleed in their brain. The study is for patients who in the opinion of the neurosurgeon could benefit equally from early surgery or initial conservative treatment.

What does the study involve?
Patients will be randomly put into either the 'early surgery' group or the 'initial conservative' group, decided by a computer system. Those who are in the 'early surgery' group will have an operation to remove the bleed in the brain within 12 hours. Those in the 'initial conservative treatment' group will be monitored closely and if necessary, receive an operation later on. Patients will have another CT scan done 5 days later. The doctor will complete a form at 2 weeks /discharge. The patient will be sent a postal questionnaire at 6 months to fill in and return.

What are the possible benefits and risks of participating?
The usual possible risks associated with having an operation or being managed 'conservatively' apply to this study. We cannot promise that the study will help the patients taking part, but the information we get might improve treatment of future patients with brain haemorrhage.

Where is the study run from?
This international study is co-ordinated by Newcastle University, Newcastle upon Tyne, UK. This study has 126 hospitals around the world taking part, from 39 countries.

When is the study starting and how long is it expected to run for?
The STICH II trial opened for recruitment in January 2007; it will finish when 600 patients have been recruited and their 6-month follow-up is complete. Publication of the results is planned in 2013.

Who is funding the study?
The trial was funded by the Medical Research Council (MRC) and funding has now been transferred to the NIHR EME programme (UK).

Who is the main contact?
The main contact is the team at the co-ordinating centre here in Newcastle. Their contact details can be found on our website at: http://research.ncl.ac.uk/stich/ or you can email the team at stich@ncl.ac.uk

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
MRC G0501444/NUTH 3545

Study information

Scientific Title
Surgical Trial in Lobar Intracerebral Haemorrhage

Acronym
STICH II

Study objectives
To establish whether a policy of earlier surgical evacuation of the haematoma in selected patients with spontaneous lobar IntraCerebral Haemorrhage (ICH) will improve outcome compared to a policy of initial conservative treatment. The trial will also help to better define the indications for early surgery.

The protocol can be found at: http://research.ncl.ac.uk/stich/

Ethics approval required
Old ethics approval format

Ethics approval(s)
Multi-Centre Research Ethics Committee for Scotland (Committee A), 28/08/2006, REC ref: 06/MRE00/66

Study design
International multicentre randomised parallel group trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Spontaneous intracerebral haemorrhage confined to the lobar region

Interventions
The trial intervention is early evacuation of the haematoma by craniotomy, combined with appropriate best medical treatment versus best medical treatment, combined with delayed evacuation only if it becomes necessary later.

In the STICH trial, 26% of patients crossed over from conservative treatment to surgery but we have little information about the reasons for crossover. This is a major problem with surgical trials and crossovers of this size are common (Fairbank et al., 2005). The aim is to have fewer crossovers in STICH II. We will collect further information about the status (GCS and focal signs) of all patients through the first 5 days of their trial progress in order to be able to monitor the change in status that leads to a change in equipoise for the treating neurosurgeon.

Intervention Type
Mixed

Primary outcome(s)
Unfavourable outcome will be death or severe disability, which will be defined using a prognosis-based eight-point Glasgow Outcome Scale/Modified Rankin Scale (Mendelow et al., 2003, 2005)

Key secondary outcome(s))
1. Mortality
2. Modified Rankin Scale
3. Barthel's Index of Activities of daily living (BAI)
4. EuroQol Quality of Life Health Survey
5. Survival

Completion date
31/03/2013

Eligibility

Key inclusion criteria

1. Evidence of a spontaneous lobar ICH on Computed Tomography (CT) scan (within 1 cm of the cortical surface)
2. Patient within 48 hours of ictus
3. The 'clinical uncertainty principle' is used: only patients for whom the responsible neurosurgeon is uncertain about the benefits of either treatment are eligible. These include patients with a haematoma volume of between 10 and 100 ml and a best motor score on the Glasgow Coma Score (GCS) of five or six together with some eye opening

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
1. Clear evidence that the haemorrhage is due to an aneurysm or angiographically proven arteriovenous malformation
2. Intraventricular haemorrhage of any sort
3. ICH secondary to tumour or trauma
4. Basal ganglia, thalamic, cerebellar or brainstem haemorrhage or extension of a lobar haemorrhage into any of these regions
5. Severe pre-existing physical or mental disability or severe co-morbidity which might interfere with assessment of outcome
6. If surgery cannot be performed within 12 hours

Date of first enrolment
01/01/2007

Date of final enrolment
31/03/2013

Locations

Countries of recruitment
United Kingdom

England

Armenia

Australia

China

Czech Republic

Egypt

Germany

Greece

Hungary

India

Italy

Japan

Latvia

Lithuania

Malaysia

Mexico

Nepal

North Macedonia

Pakistan

Poland

Romania

Russian Federation

Singapore

Spain

Sri Lanka

Türkiye

United States of America

Study participating centre

Newcastle University
Newcastle upon Tyne
United Kingdom
NE2 4AE

Sponsor information

Organisation
Newcastle upon Tyne Hospitals NHS Trust (UK)

ROR
https://ror.org/05p40t847

Funder(s)

Funder type
Government

Funder Name
Efficacy and Mechanism Evaluation Programme

Alternative Name(s)
NIHR Efficacy and Mechanism Evaluation Programme, Efficacy and Mechanism Evaluation (EME), EME

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
Not provided at time of registration

IPD sharing plan summary

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	03/08/2013		Yes	No
Protocol article	protocol	17/05/2011		Yes	No

Other publications	retrospective methods analysis	01/02/2018		Yes	No
Other publications		10/05/2023	10/05/2023	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Statistical Analysis Plan	statistical analysis plan	21/11/2012		No	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes