

# Randomised Evaluation of Surgery with Craniectomy for patients Undergoing Evacuation of Acute Subdural Haematoma (RESCUE-ASDH)

<b>Submission date</b> 31/07/2014	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 31/07/2014	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 25/06/2024	<b>Condition category</b> Injury, Occupational Diseases, Poisoning	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

Plain English summary as of 04/12/2018:

### Background and study aims

It is estimated that 4,000 head-injured patients have emergency brain surgery each year in the NHS. Two-thirds of head-injured patients requiring emergency surgery have a blood clot between the outer lining of the brain and the brain itself. This is called an acute subdural haematoma (ASDH). The pressure this clot puts on the brain can be life threatening, so an urgent operation is needed to remove it. When an ASDH is surgically removed, a piece of skull can be left out or replaced before closing the skin. When a piece of skull is replaced before closing the skin, the operation is named craniotomy. On the other hand, when a piece of skull is left out, the operation is named decompressive craniectomy (DC). The advantage of a DC is that it is more effective in controlling brain swelling, which is often a problem in the days after the operation. After a few months, the patient has another operation to rebuild the skull (with the patient's own bone or an artificial material). The advantage of a craniotomy is that the patient will not need a later operation to rebuild the skull. However, craniotomy may fail to control the brain swelling in some patients. All neurosurgeons are capable of performing both types of operation. Currently, there is no high-quality evidence showing if one operation is better than the other. This study aims to provide this much needed evidence.

### Who can participate?

Adult patients with head injuries and acute subdural haematoma can take part.

### What does the study involve?

Patients will be randomly allocated to one of the two above mentioned treatments. Participants of the study will fill in a short questionnaire at 6 months and 12 months after the initial injury this is the only additional thing they will be asked to do. This questionnaire will help us find out about their recovery.

What are the possible benefits and risks of participating?

There are no direct benefits for study participants. However, the study may help doctors in the future decide which operation to use for patients who sustain severe brain injury with an acute subdural haematoma. Both types of operation are currently carried out routinely for patients with ASDH. The risks to participants are minimal. If there is a significant brain swelling preventing safe replacement of the bone flap, the patient will not be allocated but will have the bone flap left out as per standard clinical practice. Moreover, patients allocated to undergo craniotomy who go on to develop brain swelling due to their underlying injury will be allowed to return to the operating theatre to have the bone flap removed if this is deemed necessary by the clinical team.

Where is the study run from?

The lead site is Addenbrookes Hospital, Cambridge. Recruitment will be taking place across UK and international sites.

When is the study starting and how long is it expected to run for?

The study will start in October 2014 and will run until April 2020.

Who is funding the study?

National Institute for Health Research (NIHR), UK.

Who is the main contact?

Miss Tapiwa Tungamirai

tapiwa.tungamirai@addenbrookes.nhs.uk

Previous plain English summary:

Background and study aims

It is estimated that 4,000 head-injured patients have emergency brain surgery each year in the NHS. Two-thirds of head-injured patients requiring emergency surgery have a blood clot between the outer lining of the brain and the brain itself. This is called an acute subdural haematoma (ASDH). The pressure this clot puts on the brain can be life threatening, so an urgent operation is needed to remove it. When an ASDH is surgically removed, a piece of skull can be left out or replaced before closing the skin. When a piece of skull is replaced before closing the skin, the operation is named craniotomy. On the other hand, when a piece of skull is left out, the operation is named decompressive craniectomy (DC). The advantage of a DC is that it is more effective in controlling brain swelling, which is often a problem in the days after the operation. After a few months, the patient has another operation to rebuild the skull (with the patient's own bone or an artificial material). The advantage of a craniotomy is that the patient will not need a later operation to rebuild the skull. However, craniotomy may fail to control the brain swelling in some patients. All neurosurgeons are capable of performing both types of operation. Currently, there is no high-quality evidence showing if one operation is better than the other. This study aims to provide this much needed evidence.

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Where is the study run from?

The list will be updated later once more sites join the study. Following are the study sites in the UK:

1. Addenbrookes Hospital, Cambridge
2. Derriford Hospital, Plymouth
3. John Radcliffe Hospital, Oxford
4. King's College Hospital, London
5. Leeds General Infirmary, Leeds
6. Queen Elizabeth Hospital, Birmingham
7. Royal Hallamshire Hospital, Sheffield
8. Salford Royal Hospital, Manchester
9. Southampton General Hospital, Southampton
10. St George's Hospital, London
11. St Marys Hospital, London
12. The Walton Centre, Liverpool

When is the study starting and how long is it expected to run for?

The study will start in October 2014 and will run until June 2020.

Who is funding the study?

National Institute for Health Research (NIHR), UK.

Who is the main contact?

Carol Davis-Wilkie, [carol.daviswilkie@addenbrookes.nhs.uk](mailto:carol.daviswilkie@addenbrookes.nhs.uk)

## Contact information

### Type(s)

Public

### Contact name

Ms Carol Davis-Wilkie

### Contact details

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## **Additional identifiers**

### **Clinical Trials Information System (CTIS)**

Nil known

### **Integrated Research Application System (IRAS)**

156623

### **ClinicalTrials.gov (NCT)**

Nil known

### **Protocol serial number**

RESCUE-ASDH14, IRAS 156623

## **Study information**

### **Scientific Title**

Randomised Evaluation of Surgery with Craniectomy for patients Undergoing Evacuation of Acute Subdural Haematoma (RESCUE-ASDH)

### **Acronym**

RESCUE-ASDH

### **Study objectives**

Principal research question: does decompressive craniectomy lead to better functional outcomes in comparison to craniotomy for adult head-injured patients undergoing evacuation of an acute subdural haematoma?

### **Ethics approval required**

Old ethics approval format

### **Ethics approval(s)**

14/NW/1076; First MREC approval date 17/07/2014

### **Study design**

Randomised; Interventional; Design type: Treatment

### **Primary study design**

Interventional

### **Study type(s)**

Treatment

### **Health condition(s) or problem(s) studied**

Acute subdural haematoma

## **Interventions**

Following enrolment in the study, suitability for randomisation will be assessed in the operating room by the operating neurosurgeon. A secure web-based randomisation service will be used for the randomisation of suitable patients. The following information will be required in order to randomise a patient: age, best pre-intubation Glasgow Coma Scale (GCS), pre-operative pupillary reactivity, CT findings. Patients unsuitable for randomisation (e.g. when significant brain swelling prevents safe replacement of the piece of skull) will have the operation deemed to be in their best interests by the operating neurosurgeon.

Following discharge from the acute setting (neurosurgical unit), patients will be followed up at 6 and 12 months post-injury with the extended Glasgow Outcome Scale (GOSE) and the EQ-5D questionnaires. Follow-up will be undertaken by postal questionnaires. However, in some cases a structured telephone interview will need to be undertaken by a blinded assessor, for example, if there are practical difficulties with filling in or returning the form

## **Intervention Type**

Other

## **Phase**

Not Applicable

## **Primary outcome(s)**

Extended Glasgow outcome scale; Timepoint(s): at 12 months post-injury

## **Key secondary outcome(s)**

1. Extended Glasgow outcome scale at 6 months post-injury
2. Quality of life (EQ-5D) at discharge from neurosurgical unit (NSU), 6 and 12 months post-injury
3. Glasgow Coma Scale (GCS) on discharge from the intensive care unit (ICU) and from NSU
4. Length of stay in ICU, neurosurgical and rehabilitation unit
5. Therapy Intensity Level (IMPACT-TBI scale) in the ICU
6. Discharge destination from NSU
7. Mortality
8. Serious adverse events and surgical complications during index admission
9. Cranial surgery within 2 weeks after randomisation
10. Subsequent readmissions to the NSU within the 12 months follow-up period
11. Hydrocephalus requiring shunt insertion within the 12 months follow-up period
12. Healthcare services utilisation over 12 months
13. Detailed economic evaluation

## **Completion date**

30/04/2020

## **Eligibility**

### **Key inclusion criteria**

Participant inclusion criteria as of 04/12/2018:

1. Adult head-injured patients (>16 years)
2. Acute subdural haematoma on CT\*
3. The admitting neurosurgeon feels that the haematoma needs to be evacuated with a large

bone flap (recommended size  $\geq 11$  cm anteroposterior diameter) either by a craniotomy or decompressive craniectomy

\*Patients with additional lesions (e.g. intracerebral haemorrhage, contusions) can be included

Previous participant inclusion criteria:

1. Adult head-injured patients (>16 years)

2. Acute subdural haematoma on CT\*

3. The admitting neurosurgeon feels that the haematoma needs to be evacuated either by a craniotomy or decompressive craniectomy (bone flap at least 11 cm in both instances )\*

\*Patients with additional lesions (e.g. intracerebral haemorrhage, contusions) can be included

### **Participant type(s)**

Patient

### **Healthy volunteers allowed**

No

### **Age group**

Adult

### **Lower age limit**

16 years

### **Sex**

All

### **Total final enrolment**

463

### **Key exclusion criteria**

Participant exclusion criteria as of 04/12/2018:

1. Bilateral acute subdural haematomas both requiring evacuation

2. Previous enrolment in the RESCUE-ASDH study

3. Severe pre-existing physical or mental disability or severe co-morbidity which would lead to a poor outcome even if the patient made a full recovery from the head injury

Previous participant exclusion criteria:

1. Bilateral unresponsive dilated pupils of  $\geq 5$  mm and/or brainstem injuries on CT

2. Uncorrected coagulopathy

3. Bilateral acute subdural haematomas both requiring evacuation

4. Previous enrolment in the RESCUE-ASDH study

5. Severe pre-existing physical or mental disability or severe co-morbidity which would lead to a poor outcome even if the patient made a full recovery from the head injury

### **Date of first enrolment**

01/10/2014

### **Date of final enrolment**

30/04/2019

# Locations

## Countries of recruitment

United Kingdom

England

Scotland

Wales

Australia

Canada

Germany

Greece

Hungary

India

Italy

Malaysia

Pakistan

Singapore

Spain

United States of America

## Study participating centre

### Addenbrookes Hospital

Cambridge University Hospitals NHS Foundation Trust

Hills Road

Cambridge

United Kingdom

CB2 0QQ

## Study participating centre

### Derriford Hospital

Derriford Rd

Plymouth  
United Kingdom  
PL6 8DH

**Study participating centre**  
**John Radcliffe Hospital**  
Headley Way,  
Headington  
Oxford  
United Kingdom  
OX3 9DU

**Study participating centre**  
**King's College Hospital**  
Denmark Hill,  
Brixton  
London  
United Kingdom  
SE5 9RS

**Study participating centre**  
**Leeds General Infirmary**  
Great George Street  
Leeds  
United Kingdom  
LS1 3EX

**Study participating centre**  
**Queen Elizabeth Hospital**  
Mindelsohn Way  
Edgbaston  
Birmingham  
United Kingdom  
B15 2TH

**Study participating centre**  
**Royal Hallamshire Hospital**  
Glossop Road  
Sheffield  
United Kingdom  
S10 2JF



**Study participating centre**  
**Salford Royal Hospital**  
Stott Lane  
Manchester  
United Kingdom  
M6 8HD

**Study participating centre**  
**Southampton General Hospital**  
Tremona Road  
Southampton  
United Kingdom  
SO16 6YD

**Study participating centre**  
**St George's Hospital**  
Blackshaw Road  
London  
United Kingdom  
SW17 0QT

**Study participating centre**  
**St Mary's Hospital**  
Praed Street  
London  
United Kingdom  
W2 1NY

**Study participating centre**  
**The Walton Centre**  
Lower Lane  
Liverpool  
United Kingdom  
L9 7LJ

**Study participating centre**  
**University Hospital of Wales**  
Heath Park

Cardiff  
United Kingdom  
CF14 4XW

**Study participating centre**  
**Queen's Medical Centre**  
Derby Road  
Nottingham  
United Kingdom  
NG7 2UH

**Study participating centre**  
**Royal Sussex County Hospital**  
Barry Building,  
Eastern Road  
Brighton  
United Kingdom  
BN2 5BE

**Study participating centre**  
**James Cook University Hospital**  
Marton Road  
Middlesbrough  
United Kingdom  
TS4 3BW

**Study participating centre**  
**Queen's Hospital**  
Rom Valley Way  
Romford  
United Kingdom  
RM7 0AG

**Study participating centre**  
**Royal London Hospital**  
Whitechapel Road,  
Whitechapel  
London  
United Kingdom  
E1 1BB

**Study participating centre**

**Southmead Hospital**

Southmead Road,  
Westbury-on-Trym  
Bristol  
United Kingdom  
BS10 5NB

**Study participating centre**

**University Hospital Coventry**

Clifford Bridge Road  
Bristol  
United Kingdom  
CV2 2DX

**Study participating centre**

**Ninewells Hospital**

James Arrott Drive  
Dundee  
United Kingdom  
DD2 1SY

**Study participating centre**

**Hull Royal Infirmary**

Anlaby Road  
Hull  
United Kingdom  
HU3 2JZ

**Study participating centre**

**Western General Hospital**

Crewe Road  
Edinburgh  
United Kingdom  
EH4 2XU

**Study participating centre**

**Queen Elizabeth University Hospital**

1345 Govan Road

Glasgow  
United Kingdom  
G51 4TF

**Study participating centre**  
**Royal Preston Hospital**  
Sharoe Green Lane,  
Fulwood  
Preston  
United Kingdom  
PR2 9HT

**Study participating centre**  
**Royal Victoria Infirmary**  
Queen Victoria Road  
Newcastle upon Tyne  
United Kingdom  
NE1 4LP

**Study participating centre**  
**Singapore General Hospital**  
Outram Road  
Singapore  
Singapore  
169608

**Study participating centre**  
**Tan Tock Seng Hospital**  
11 Jln Tan Tock Seng  
Singapore  
Singapore  
308433

**Study participating centre**  
**Beth Israel Deaconess Medical Center**  
330 Brookline Avenue  
Boston  
United States of America  
02215

**Study participating centre**  
**The University of Texas Southwestern Medical Center**  
5323 Harry Hines Blvd  
Dallas  
United States of America  
75390

**Study participating centre**  
**University of Malaya Medical Centre**  
Lembah Pantai  
Kuala Lumpur  
Malaysia  
59100

**Study participating centre**  
**Foothills Medical Centre**  
1403 29 St NW  
Calgary  
Canada  
T2N 2T9

**Study participating centre**  
**Hamilton General Hospital**  
237 Barton St E  
Hamilton  
Canada  
L8L 2X2

**Study participating centre**  
**Sunnybrook Health Sciences Centre**  
2075 Bayview Ave  
Toronto  
Canada  
M4N 3M5

**Study participating centre**  
**MedStar Washington Hospital Center**  
110 Irving St NW

Washington, DC  
United States of America  
20010

**Study participating centre**  
**University Hospital of Larissa**  
Mezourlo  
Larissa  
Greece  
41110

**Study participating centre**  
**National Institute of Mental Health and Neurosciences (NIMHANS)**  
Hosur Road  
Bangalore  
India  
560029

**Study participating centre**  
**Post Graduate Institute of Medical Education and Research (PGIMER)**  
Sector 12  
Chandigarh  
India  
160012

**Study participating centre**  
**All India Institute of Medical Sciences (AIIMS)**  
Sri Aurobindo Marg,  
Ansari Nagar,  
Ansari Nagar East  
New Delhi  
India  
110029

**Study participating centre**  
**Technische Universität München**  
Arcisstraße 21  
Munich  
Germany  
80333

**Study participating centre**  
**Hospital Universitario La Paz**  
Paseo de la Castellana,  
261  
Madrid  
Spain  
28046

**Study participating centre**  
**Littleton Adventist Hospital**  
7700 S Broadway  
Littleton  
United States of America  
80122

**Study participating centre**  
**The Alfred Hospital**  
55 Commercial Rd  
Melbourne  
Australia  
3004

**Study participating centre**  
**Hospital Universitario 12 de Octubre**  
Av. Cordoba  
Madrid  
Spain  
28041

**Study participating centre**  
**Jacobi Medical Center and Montefiore Medical Center**  
1400 Pelham Parkway,  
South Bronx  
New York  
United States of America  
10461

**Study participating centre**

**Queen Elizabeth II Health Sciences Centre**  
1276 South Park Street  
Halifax  
Canada  
B3H 2Y9

**Study participating centre**  
**University of Pécs**  
Pécs  
Hungary  
-

**Study participating centre**  
**The Ottawa Hospital**  
Ottawa  
Canada  
-

**Study participating centre**  
**North Shore University Hospital**  
New York  
United States of America  
-

**Study participating centre**  
**Christian Medical College & Hospital**  
Vellore  
India  
-

**Study participating centre**  
**Northwest General Hospital and Research Center**  
Peshawar  
Pakistan  
-

**Study participating centre**  
**Humanitas Research Hospital**  
Milan



Italy  
-

## Sponsor information

**Organisation**  
Cambridge University Hospitals NHS Foundation Trust & University of Cambridge (UK)

**ROR**  
<https://ror.org/04v54gj93>

## Funder(s)

**Funder type**  
Government

**Funder Name**  
NIHR Health Technology Assessment Programme - HTA (UK); Grant Codes: 12/35/57

## Results and Publications

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

**IPD sharing plan summary**  
Not provided at time of registration

Study outputs					
Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>	Cost evaluation	23/04/2023	25/04/2023	Yes	No
<a href="#">Results article</a>		16/06/2024	25/06/2024	Yes	No
<a href="#">HRA research summary</a>	Participant information sheet		28/06/2023	No	No
<a href="#">Participant information sheet</a>		11/11/2025	11/11/2025	No	Yes
<a href="#">Plain English results</a>			20/11/2023	No	Yes