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

Submission date
31/07/2014

Recruitment status
No longer recruiting

Registration date
31/07/2014

Overall study status
Completed

Last Edited
25/06/2024

Condition category
Injury, Occupational Diseases, Poisoning

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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
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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

Contact information

Type(s)
Public

Contact name
Ms Carol Davis-Wilkie

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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 beevacuated with a large

bone flap (recommended size ≥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 ≥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
Ottowa
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?
Results article	Cost evaluation	23/04/2023	25/04/2023	Yes	No
Results article		16/06/2024	25/06/2024	Yes	No
HRA research summary			28/06/2023	No	No
Plain English results			20/11/2023	No	Yes