

STAGE 1 (TO BE RETURNED* WITHIN 3 DAYS OF ENROLMENT)



PATIENT DETAILS

Participant Initials: Date of Birth: / / Subject ID: -

ELIGIBILITY REVIEW

INCLUSION CRITERIA

To be included in the trial, the following must all be answered YES

1. Patients > 16 years ☐ Yes ☒ No
2. Acute subdural haematoma on CT ☐ Yes ☒ No
3. The admitting neurosurgeon feels that the acute subdural haematoma needs to be evacuated either by craniotomy or decompressive craniectomy (bone flap > 11 cm) * ☐ Yes ☒ No
- *Patients with additional lesions (such as intracerebral Haemorrhage/contusions) may be included*

EXCLUSION CRITERIA

To be included in the trial, the following must all be answered NO

1. Bilateral unresponsive dilated pupils of ≥ 5 mm and/or brainstem injuries on CT ☒ Yes ☐ No
2. Uncorrected coagulopathy ☒ Yes ☐ No
3. Bilateral acute subdural haematomas both requiring evacuation ☒ Yes ☐ No
4. Previous enrolment in RESCUE-ASDH study ☒ Yes ☐ No
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 ☒ Yes ☐ No

Is the participant eligible?

☐ Yes ☒ No

Name and title of Operating Surgeon

Date of eligibility review

PI to verify eligibility and sign within 3 working days of randomisation of the participant into the trial

Date signed by PI

ENROLMENT

Please use this link to access TENLEA: <http://www.rescueasdh.org>

Was the patient randomised ?

☐ Yes

☐ No

RANDOMISED PARTICIPANTS

Subject ID allotted as
(use Randomisation system output)

R -

Treatment allocated and received
(Select only one)

- ☐ 1. Craniotomy and received Craniotomy
- ☐ 2. Decompressive Craniectomy and received Decompressive Craniectomy
- ☐ 3. Craniotomy and received Decompressive Craniectomy
- ☐ 4. Decompressive Craniectomy and received Craniotomy

If option 3 or 4, please give reasons

- ☐ Intraoperative brain swelling
- ☐ Brain relaxed
- ☐ Other, please specify

Date of enrolment

OBSERVATIONAL COHORT

If not randomised, Subject ID allotted as
(use generated Subject ID)

O -

Treatment given

- ☐ 1. Craniotomy
- ☐ 2. Decompressive Craniectomy-unilateral
- ☐ 3. Decompressive Craniectomy-bilateral
- ☐ 4. Other, please specify

Please give reason why not suitable for Randomisation

- ☐ Intraoperative brain swelling
- ☐ Brain relaxed
- ☐ Other, please specify

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EARLY INJURY EVENT DETAILS

Injury Date / /
Injury Time (approx) :
(please use 24 hr clock)

Patient referred from Other centre ? ☐ NO ☐ YES (If Yes, Please fill the details below)

Referring Hospital name and address
(Name of hospital and city)

Hospital Admission Date and Time / /
(Please use 24 hr clock) :

CONSENT

Next of kin/family/ Friend available at the time of admission ☐ YES ☐ NO

Was an initial consent taken ? ☐ YES ☒ NO

Date of initial consent / /

Type of consent form filled
(Please select from the following options provided)

☐ IHP enrolment form
☐ Consultee agreement form
☐ Participant Consent form

SURGERY DETAILS

Date of Surgery / / ☐ Tick here if Surgery ended next day

Time Surgery started : **Time Surgery finished** :
(please use 24 hr clock)

Size of bone flap . (cm) **Location of ASDH** ☐ Left ☐ Right

ASDH volume ☐ 0—5 cc ☐ 5—10 cc ☐ 10—15 cc ☐ 15—20 cc ☐ >20 cc

Other haematomas evacuated ☐ No ☐ Intracerebral ☐ Extracerebral ☐ Contusions
☐ Other

Type of skin incision? ☐ Reverse Question mark ☐ T-shaped ☐ Other

Dura Closure ☐ Open ☐ Closed ☐ Duraplasty
☐ Other

Peri-operative complications ☐ No ☐ Expansions of mass lesion ☐ Development of new mass lesions
☐ Stroke ☐ Vascular Injury ☐ Other

Was intracranial monitoring device inserted ☐ No ☐ Yes, EVD ☐ Yes, Subdural/subarachnoid
☐ Yes, Epidural ☐ Yes, Parenchymal ☐ Other

Location of the Monitoring device ☐ Ipsilateral to ASDH ☐ Contralateral to ASDH

Skin Closure ☐ Stapled ☐ Sutured **Drain used ?** ☐ Yes, Subdural ☐ No drain used ☐ Yes, Subgaleal

Bone flap storage (Craniectomy patients only)
☐ Stored outside patient's body ☐ Stored in patient's body ☐ Disposed ☐ Sent for implant modelling
☐ Other

Completed by

 / /

Return forms to the RESCUE_ASDH Data Manager by email (CRF@RESCUEASDH.ORG) or fax (+44 1223 596471)

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PATIENT DETAILS

Participant Initials: Date of Birth: / / Subject ID:

CT SCAN

Date of first CT scan used for diagnosing ASDH / /

Time of CT Scan (approx) :

CT SCAN RESULTS

Midline Shift (Select only one) ☐ No ☐ ≤ 5.0 mm ☐ 5.1–10.0 mm ☐ >10 mm

Obliteration of the third Ventricle or basal cisterns (Select only one) ☐ Normal ☐ Compressed ☐ Absent

High or mixed density parenchymal lesions ≤ 25 cc (e.g. Contusions, petechial haemorrhages) ☐ No ☐ Yes

Interventricular blood ☐ No ☐ Yes

Traumatic SAH ☐ No ☐ Yes

Extradural haematoma (Select only one) ☐ Absent ☐ ≤ 25 cc ☐ > 25 cc

Subdural haematoma (Select only one) ☐ Absent ☐ ≤ 25 cc ☐ > 25 cc

Intracerebral Haematoma (Select only one) ☐ Absent ☐ ≤ 25 cc ☐ > 25 cc

Posterior fossa haematoma ☐ No ☐ Yes

Depressed Skull fracture ☐ No ☐ Yes

Completed by

GLASGOW COMA SCALE (GCS) (pre-randomization)

BEST GCS BEFORE SEDATION OR INTUBATION

EYE OPENING

☐ E4 Spontaneously

☐ E3 To Speech

☐ E2 To Pain

☐ E1 None

☐ Untestable

☐ Closed to swelling

☐ Other _____

☐ Unknown

MOTOR

☐ M6 Obeys Command

☐ M5 Localized pain

☐ M4 Flexion withdrawal

☐ M3 Abnormal flexion

☐ M2 Abnormal extension

☐ M1 None

☐ Untestable

☐ Deep sedation/paralysis

☐ Other _____

☐ Unknown

VERBAL

☐ V5 Oriented

☐ V4 Confused

☐ V3 Inappropriate words

☐ V2 Incomprehensible sound

☐ V1 None

☐ Untestable

☐ Tracheotomy/
Endotrach tube

☐ Other _____

☐ Unknown

PUPILS

LEFT EYE

Reactivity

☐ - NEGATIVE

☐ + POSITIVE

☐ UNTESTABLE

☐ UNKNOWN

SIZE (1– 9 mm)

RIGHT EYE

Reactivity

☐ - NEGATIVE

☐ + POSITIVE

☐ UNTESTABLE

☐ UNKNOWN

SIZE (1– 9 mm)

DISCHARGE DESTINATION AFTER OPERATION

Discharge destination after operation
(Select any one)

☐ Died, please give the Principal cause →

☐ ICU

☐ NSU/Ward

☐ Different Hospital

☐ Unknown

☐ Other, _____

☐ Head Injury/ Initial Injury

☐ Head Injury/
Secondary Intracranial damage

☐ Systemic Trauma

☐ Medical Complications

☐ Unknown

☐ Other, _____

/ /