STITCH (TRAUMA)

Surgical Trial in Traumatic Intracerebral Haemorrhage

Newcastle University

PAGE 1

DISCHARGE / 2 WEEK FOLLOW-UP FORM

Patient Number

STITCH

This form is to be completed at two weeks post randomisation, or at discharge of the patient from your Neurosurgical Centre, whichever is the sooner. Please answer questions, ticking affirmative/filling in appropriate boxes.

Hospital Name ____ Centre Number ____

Patient Initials ____ Date of Birth *(dd/mm/yy)*: / / Sex ____ *f=female, m=male*

CURRENT STATUS OF PATIENT

Please tick one box and give appropriate date:

Alive ☐ Dead ☐ Date of completion of the discharge form *(dd/mm/yy)* / /

If alive, status at 2 weeks/ discharge (please tick):

Vegetative ☐ Severely Disabled (dependent) ☐ Moderately Disabled (independent) ☐ Good Recovery ☐

Glasgow Coma Score at 2 weeks/ discharge:

Eye ☐ *1) No eye opening, 2) Opening to pain, 3) Opening to speech, 4) Spontaneous eye opening*

Verbal ☐ *1) None, 2) Incomprehensible sounds, 3) Inappropriate words, 4) Confused, 5) Orientated*

Motor ☐ *1) No motor response, 2) Extension to pain, 3) Flexion to pain, 4) Withdraws from pain, 5) Localises to pain, 6) Obeys commands*

Location of Patient: Please tick <u>one</u> box and fill in the date:

Still in neurosurgical ward..... ☐ / /
** should be 2 weeks post randomisation*

Discharged from hospital..... ☐ / /
*** record discharge address and Tel. No. on contact sheet*

Discharged to **(please tick):** Rehab unit ☐ Nursing home ☐ Home ☐ Other ☐ If other, specify_____ N/A ☐

Transferred from neurosurgical ward to other hospital or ward. ☐ / /
****record name of hospital ward, Tel .No. on contact sheet*

Transferred to **(please tick):** General Ward ☐ Other Hospital ☐ Other ☐ If other, specify_____ N/A ☐

If dead please record the date of death *(dd/mm/yy)*..... / /

Cause of death (please write the most likely number in the box).....

1 = Head injury/initial injury *2= Head Injury / secondary intracranial damage*
3= Systemic Trauma *4 =Medical Complications*
5= Other
If other, specify_____

If patient has died please remember to complete a MAJOR EVENT FORM and return this to the STITCH (Trauma) Office. FAX: +44 (0)191 222 5762

Patient Number

PATIENT DETAILS BEFORE THE HEAD INJURY OCCURRED

Please tick:

Was the patient left or right handed? : Left ☐ Right ☐

Primary person that the patient lives with and who can act as a contact/next of kin/carer (please choose the lowest most appropriate number to record in the box): ☐

1= Not applicable- lives alone
2=spouse/significant other partner
3= parents
4=siblings
5=child/children
6=other (please specify)_____

SIGNIFICANT MEDICAL HISTORY BEFORE THE INJURY

Please tick yes or no and explain further in the box below:

	Yes	No		Yes	No		Yes	No
Cardiovascular	☐	☐	Endocrine	☐	☐	Eye, Ear, Nose & Throat	☐	☐
Gastrointestinal	☐	☐	Hematologic	☐	☐	Hepatic	☐	☐
Musculoskeletal	☐	☐	Neurologic	☐	☐	Previous TBI	☐	☐
Oncologic	☐	☐	Pulmonary	☐	☐	Psychiatric	☐	☐
Renal	☐	☐	Social History	☐	☐	Developmental History	☐	☐
Epilepsy	☐	☐	Anti-Epileptics	☐	☐			

Pre ICH Rankin Score (please write the appropriate number in the box)..... ☐
0=Well, no symptoms, 1=Minor symptoms not affecting lifestyle, 2=Minor handicap but independent in self care, 3=Moderate handicap, requiring a little help with ADL (Activities Daily Living), 4=Needing a lot of help with ADL, 5=Needing constant attention day and night.

Pre ICH Mobility (please write appropriate number in the box)..... ☐
1=Able to walk 200m outside, 2=Able to walk indoors, 3=Unable to walk without help

ANTICOAGULANT/ANTITHROMBOTIC TREATMENT AT THE TIME OF THE TRAUMATIC ICH

Was the patient taking/given:

Anticoagulant treatment *(e.g. warfarin/heparin)*	Yes ☐	No ☐	Initial INR ☐	
Antiplatelet therapy *(e.g. aspirin/Clopidogrel/Dipyridamole)*	Yes ☐	No ☐		
Recent thrombolytic therapy which might have contributed to ICH	Yes ☐	No ☐		

PLEASE COMPLETE FOR ALL PATIENTS

Patient Number

INJURY DETAILS

Date of injury *(dd/mm/yy)* / / Time of injury *(24 hour clock)* :

Cause of Injury (please tick):

Road Traffic Accident ☐ Fall domestic ☐ Fall outside home ☐ Work ☐
Violence/Assault ☐ Suicide attempt ☐ Sport/Recreation ☐
Other *(please give details)*.....

If Road Traffic Accident, was the victim (please tick):

Motor Vehicle Occupant ☐ Pedestrian ☐ Cyclist ☐ Moped/Scooter ☐
Motorbike ☐
Other *(please give details)*.....

Mechanism of Injury (please tick):

- ☐ Acceleration/Deceleration
- ☐ Direct Impact
- ☐ Crush
- ☐ Blast
- ☐ Penetrating
- ☐ Fall
  - ☐ Fall – ground floor level
  - ☐ Fall from height > 1 meter (3ft)

Injuries and Injury Severity:

Body Region	Severity *Please select a number from the list below	Surgery Required? (Apart from the trial) Please tick	
		YES	NO
External (skin)			
Head (incl. brain and neck)			
Face			
Chest			
Abdomen/pelvic contents			
Extremities			
Spine			

**0. Not affected*
1.Minor: no treatment needed
2. Moderate: requires only outpatient treatment
3.Serious: requires non-ICU hospital admission
4. Severe: requires ICU observation and/or basic treatment
5. Critical: requires intubation, mechanical ventilation or vasopressors for blood pressure support.
6. Maximal: not survivable.

REFERRAL DETAILS:

***Tick here if the patient went to any other hospital(s) before arriving at the study centre.*

☐ Primary admission*

**Tick here if the patient came directly to the study centre*

☐ Secondary admission**

ARRIVAL AT FIRST HOSPITAL:

Date of arrival first hospital: *(dd/mm/yy)* / /

Time of Arrival *(24 hour clock):* :

ARRIVAL AT STUDY CENTRE:

Date of arrival study centre: (dd/mm/yy) / /

Time of Arrival *(24 hour clock)*: :

Patient Number

PLEASE COMPLETE FOR ALL PATIENTS

EMERGENCY SERVICE: THERAPEUTIC PROCEDURES

What emergency services were provided for the airway (please tick all that apply):-

No specific treatment ☐ Oxygen ☐ Intubation ☐

What secondary insults occurred as a result of the head injury and before the patient was randomised to the trial? (Please tick all that apply):

	Yes	No
Hypoxic	☐	☐
Hypotensive	☐	☐
Hypothermic	☐	☐
Cardiac Arrest	☐	☐

INITIAL NEUROLOGICAL ASSESSMENT

Was there an initial loss of consciousness? (Please tick):

Yes ☐ No ☐ Unknown ☐

If yes, please give duration* ☐

**1 = < 1 minute 2 = 1 -29 minutes 3 = 30 minutes – 24 hours 4 = > 24 hours*

Is there pre traumatic amnesia? (Please tick)

Yes ☐ No ☐ Unknown ☐

If yes, please give duration* ☐

**1 = < 1 minute 2 = 1 -29 minutes 3 = 30 minutes – 24 hours 4 = > 24 hours*

Is there post traumatic amnesia? (Please tick)

Yes ☐ No ☐ Unknown ☐

If yes, please give duration* ☐

**1 = < 1 minute 2 = 1 -29 minutes 3 = 30 minutes – 24 hours 4 = > 24 hours*

IF THIS PATIENT WAS RANDOMISED TO EARLY SURGERY PLEASE GO TO PAGE 5.

IF THIS PATIENT WAS RANDOMISED TO INITIAL CONSERVATIVE TREATMENT PLEASE GO TO PAGE 6.

Patient Number

FOR PATIENTS RANDOMISED TO EARLY SURGERY ONLY

Was early ICH Evacuation performed? Yes ☐ No* ☐

If yes, please complete the top half of this page. If no, please give more details in the lower half of this page.

ICH Evacuation performed on:

Date *(dd/mm/yy)* / / Time*(24 hour clock)* :

ICH evacuation method (please write appropriate number in box) ☐

1=craniotomy, 2= other: specify.....

Was the bone flap replaced? Yes ☐ No ☐

Was any other neurosurgical procedure performed?

Yes ☐ No ☐ Date *(dd/mm/yy)* / /

Was any non-cranial surgery performed? Yes ☐ No ☐

Please give details of the other neurosurgery/non cranial surgery below:

.....

NEUROLOGICAL STATUS IMMEDIATELY PRIOR TO EVACUATION

Patient paralysed and sedated? Yes ☐ No ☐

Glasgow Coma Score prior to evacuation:

Eye Opening (1-4) ☐ Best Verbal Response (1-5) ☐ Best Motor Response (1-6) ☐

***If evacuation was NOT done, please record the following details about this decision:**

Reason (please describe briefly below):

.....

Date of decision *(dd/mm/yy)* / / Time of decision *(24 hour clock)* :

Glasgow Coma Score when the decision was taken not to evacuate:

Eye Opening (1-4) ☐ Best Verbal Response (1-5) ☐ Best Motor Response (1-6) ☐

If evacuation was NOT done was this because of evidence of neuroworsening?*

Yes ☐ No ☐ Date of neuroworsening (dd/mm/yy) / /

Time of neuroworsening (24 hour clock) :

**Neuroworsening is defined as:*
1. A spontaneous decrease in the Glasgow Coma Scale motor score ≥ 2 points (compared with previous examination), or
2. A new loss of pupillary reactivity, development or pupillary asymmetry ≥2mm, or
3. Deterioration in neurological or CT status sufficient to warrant immediate medical or surgical intervention

If there WAS neuroworsening which of the following occurred? (please tick all that apply):

☐ Decrease in motor score ≥ 2 points
☐ Development of pupillary abnormalities
☐ Other neurological and/or CT deterioration

What other action was taken as a result of the neuroworsening? (please tick all that apply):

☐ None ☐ Unscheduled CT scan ☐ Change in medical therapy

PLEASE TURN TO PAGE 7

Patient Number

FOR PATIENTS RANDOMISED TO CONSERVATIVE TREATMENT ONLY

Was delayed ICH evacuation necessary? Yes* ☐ No* ☐ *If yes, please complete this page. If no, please go to the next page.*

If YES please give date *(dd/mm/yy)* / / and time *(24 clock)* :

ICH evacuation method (please write appropriate number in box): ☐

1=craniotomy, 2=other: specify.....

Was the bone flap replaced? Yes ☐ No ☐

Was any other neurosurgical procedure performed?

Yes ☐ No ☐ Date *(dd/mm/yy)* / /

Was any non-cranial surgery performed? Yes ☐ No ☐

Please give details of the other neurosurgery/non cranial surgery below:

.....

NEUROLOGICAL STATUS IMMEDIATELY PRIOR TO EVACUATION

Patient paralysed and sedated? Yes ☐ No ☐

Glasgow Coma Score immediately prior to evacuation:

Eye Opening (1-4) ☐ Best Verbal Response (1-5) ☐ Best Motor Response (1-6) ☐

If evacuation WAS done, please record the following additional details about this decision:
Reason (please describe briefly below):

.....

Date of decision *(dd/mm/yy)* / / Time of decision *(24 hour clock)* :

Glasgow Coma Score when the decision was taken to evacuate:

Eye Opening (1-4) ☐ Best Verbal Response (1-5) ☐ Best Motor Response (1-6) ☐

If evacuation WAS done was this because of evidence of neuroworsening?*

Yes ☐ No ☐ Date of neuroworsening (dd/mm/yy) / /

Time of neuroworsening (24 hour clock) :

**Neuroworsening is defined as:*
1. A spontaneous decrease in the Glasgow Coma Scale motor score ≥ 2 points (compared with the previous examination) or
2. A new loss of pupillary reactivity, development or papillary symmetry ≥2mm, or
3. Deterioration in neurological or CT status sufficient to warrant immediate medical or surgical intervention

If there WAS neuroworsening which of the following occurred (please tick all that apply):

☐ Decrease in motor score ≥ 2 points
☐ Development of pupillary abnormalities
☐ Other neurological and/or CT deterioration

What other action was taken as a result of the neuroworsening? (please tick all that apply):

None ☐ Unscheduled CT scan ☐ Change in medical therapy ☐

PLEASE TURN TO PAGE 7

Patient Number

MONITORING AND NEUROLOGICAL ASSESSMENT

For all patients at all hospitals please record the following daily from the day before randomisation (if available):

(randomisation date=day 0)	Day -1	Day 0	Day 1	Day 2	Day 3	Day 4	Day 5
Date							
GCS - best eye (1-4)							
GCS - best verbal (1-5)							
GCS - best motor (1-6)							
Affected Arm*							
Affected Leg*							
Speech**							
Pupils***							
Highest temperature (^{o}C)							
Lowest O2 saturation (if recorded at your centre)							

**1=normal, 2= weak, 3= paralysed, 8=dead, 9=alive but cannot assess*
***1= normal, 2=dysphasic, 3=aphasic, 8=dead, 9=alive but cannot assess*
****1= equal and reacting, 2= one eye only reacting, 3=no reaction from either*

Is this patient being ICP monitored? Yes ☐ No ☐

If yes, please record the following:

What device was used for ICP monitoring? (please tick):

Ventricular ☐

Camino ☐

Codman ☐

Spiegelberg ☐

Rehau-Raumedic ☐

Other (please specify) :_____

Date of implantation of ICP device *(dd/mm/yy)* / / Time of implantation (*24 hour clock*) :

Date when ICP monitoring ended for this patient *(dd/mm/yy)* / / Time ended (*24 hour clock*) :

Did the ICP/CPP monitoring influence how this patient was managed? Yes ☐ No ☐

If yes, please give details about how the ICP or CPP levels changed and what was done as a result:

If this patient was ICP/CPP monitored, please also complete the form for "Detailed ICP Monitoring"

Patient Number

USE OF HOSPITAL FACILITIES

Please indicate the number of days that the patient was in the following type of hospital wards during the first 14 days after randomisation:

☐ Days in an intensive treatment unit (ITU)

☐ Days in a high dependency unit (HDU)

☐ Days in a general neurosurgical ward

☐ Days in other ward, please specify the type of ward/facility:_____

POST RANDOMISATION EVENTS (causing clinically significant deterioration)

Please tick appropriate box for each item or code where appropriate:

	Yes	No	Date *(dd/mm/yy)*	Time *(24hr clock)*
Ischaemic Stroke……....	☐	☐	/ /	:
Pulmonary Embolism…….... *(clinically apparent)*	☐	☐	/ /	:
Deep Vein Thrombosis……....	☐	☐	/ /	:
Pneumonia……....	☐	☐	/ /	:
Post-Op Intracranial Haemorrhage…….... *(1=EDH, 2=SDH)*	☐	☐	/ /	:
Post-Op Infection…….. *(1= wound, 2= septacemia, 3=other)*	☐	☐	/ /	:
Epilepsy……..	☐	☐	/ /	:
Other *(e.g. CSF, Stroke, MI) please specify*……	☐	☐	/ /	:

Please check that the patient's scans have been sent to the STITCH Office for detailed measurement.

Randomisation CT Scan sent? Yes ☐ No ☐

5 day post randomisation CT Scan sent? Yes ☐ No ☐

Thank you very much for your assistance.

Please return the completed form and scans to:

STITCH (Trauma), Neurosurgical Trials Unit, 3-4 Claremont Terrace,
Newcastle University
Newcastle upon Tyne
NE2 4AE, U.K
FAX: +44 (0)191 222 5762