SAE/SAR Reporting Form

Cover Sheet for Information Only

Return of Cover Page NOT required with completed form

Please fax or email a copy of this form to the Coordinating Centre within 24 hours of awareness of the event at the address below:-

Dr Natalia Igosheva
RESCUE-ASDH Trial Coordinator
Addenbrooke's Hospital
Cambridge CB2 0QQ
Tel: (+44) (0)1223 254919
Fax: (+44) (0)1223 256763
Email: Natalia.igosheva@addenbrookes.nhs.uk

Sponsor address
Cambridge Clinical Trials Unit
Email: CCTU@addenbrookes.nhs.uk
Fax: 01223 256623
Chief Investigator please fax or email a copy of this form to the Clinical Trials Unit within 24 hours of receipt from site.

Trial Title: RESCUE-ASDH:Randomised Evaluation of Surgery with Craniectomy for patients Undergoing Evacuation of Acute Subdural Haematoma

Chief Investigator: Professor Peter Hutchinson
Trial Co-ordinator: Dr Natalia Igosheva

Investigator sites: please complete all WHITE sections
Chief Investigator: please complete all GREY sections

Definitions

AE: Adverse Event. Any untoward medical occurrence that happens to a patient or research participant administered a treatment which may or may not necessarily have causal relationship with this treatment.

AR: Adverse reaction. Any untoward and unintended reaction that is considered to be related to the treatment.

The Sponsor expects that all AEs and ARs are recorded on all trials from the point of Informed Consent regardless of whether a patient has yet received the treatment.

All AEs and ARs, including expected systemic and procedure-related events, should be assessed by the Investigator and recorded in detail in medical notes and Case Report Forms (CRFs)

SAE: Serious Adverse Event. Any AE or effect that : Results in death; Is life threatening; Requires hospitalisation or prolongation of existing hospitalisation; Results in persistent or significant disability/incapacity; Is a congenital anomaly/birth defect; Is an otherwise medically important event.

SAR: Serious Adverse Reaction. An SAE that is considered to be possibly, probably or definitely related to the IMP.

SUSAR: Suspected Unexpected Serious Adverse Reaction. An **adverse reaction**, which is both serious and unexpected, i.e. the nature or severity of which is not consistent with the applicable treatment and which fulfils one or more of the criteria listed above for SAE.

In this trial only Serious adverse events/reactions and surgical complications that are **Unexpected** must be reported as SAEs/SARs

Initial Reporting: For all initial reporting of unexpected SAE/SARs this form must be **completed fully or with as much information as possible** and sent to the RESCUE-ASDH Coordinator within **24 hours** of the incident occurring or being reported to the participating team.

Follow-up Information: For subsequent follow-up reporting of an unexpected SAE/SAR, **a new SAE/SAR Reporting form should be completed by the Investigator or a delegated person with just the administration details and all new or missing information only** and forwarded to the RESCUE-ASDH Coordinator as soon as possible. All SAE/Rs must be followed up until resolution.

SAE/SAR Reporting Form

Please complete details of any SAEs from the time of informed consent. For guidance on which events to report please refer to the study protocol.
Please fax or scan and email this form to the Coordinating Centre (CCTU-CT) within 24 hours of awareness.

Trial details

Study Title: RESCUE-ASDH
ISRCTN No: ISRCTN87370545
Sponsor R&D No: A093232
SAE Ref No:

Participant details

Initials:
Subject ID No:
Date of Birth: d d / m m m / y y y y
Gender: Male ☐ Female ☐

Specifics

Type of Report:
Initial Report ☐
Follow Up Report ☐

Date of site awareness: d d / m m m / y y

Has the Principal Investigator been informed of this event prior to the completion of this form? Yes ☐ No ☐

Name of person reporting:
Centre:

Serious Adverse Event

Serious Adverse Event Term:

Date of Onset: d d / m m m / y y

Outcome: ☐
1 = Recovered/ Resolved without Sequelae
2 = Ongoing
3 = Recovered/ Resolved with Sequelae
4 = Worsening
5 = Fatal
6 = Unknown

Date of Outcome: d d / m m m / y y

Severity
Mild ☐ **Moderate** ☐ **Severe** ☐

Event Summary:

Signs and Symptoms:	Signs and Symptoms:	Admission date:	d d / m m m / y y
		Discharge date	d d / m m m / y y

Why was the event serious?

- ☐ Resulted in death
- ☐ Life-threatening
- ☐ Required inpatient or prolonged existing hospitalisation
- ☐ Resulted in persistent or significant disability/incapacity
- ☐ Resulted in congenital anomaly/ birth defect
- ☐ Other Important Medical Event (Please specify)

(Provide a clear, chronological, clinical course of events from presentation to current time—including symptoms and signs at presentation/vital signs/examination findings).

Please continue on another sheet if necessary...

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Subject ID No:
Date of Birth: ☐☐/☐☐☐/☐☐☐☐ (d d m m m y y y y)

Research Procedures

Protocol Treatment(s)/Research Procedure	Date of procedure	Date of last treatment carried out prior to SAE	SAE relation to the Research Procedure/ Causality *Use codes*	If SAE is Expected/ Unexpected *Use codes*	Name of Person making decision
	☐☐/☐☐☐/☐☐ (d d m m m y y)	☐☐/☐☐☐/☐☐ (d d m m m y y)			
	☐☐/☐☐☐/☐☐ (d d m m m y y)	☐☐/☐☐☐/☐☐ (d d m m m y y)			
	☐☐/☐☐☐/☐☐ (d d m m m y y)	☐☐/☐☐☐/☐☐ (d d m m m y y)			
	☐☐/☐☐☐/☐☐ (d d m m m y y)	☐☐/☐☐☐/☐☐ (d d m m m y y)			

Codes:

Causality:
1 = Definitely
2 = Probably
3 = Possibly
4 = Unlikely
5 = Not related
6 = Unknown/ Not assessable

Expectedness:
1 = Expected
2 = Unexpected

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Subject ID No:

Date of Birth: ☐☐/☐☐☐/☐☐☐☐ (d d / m m m / y y y y)

Treatment given to manage SAE

Treatment (surgical or medication) given to manage SAE (if applicable)	Dose	Units *i.e.: mg*	Freq. *i.e.: O/D*	Route of Admin. *Use codes*	Date of treatment/first dose	End date (if applicable)
					☐☐/☐☐☐/☐☐ (d d / m m m / y y)	☐☐/☐☐☐/☐☐ (d d / m m m / y y)
					☐☐/☐☐☐/☐☐ (d d / m m m / y y)	☐☐/☐☐☐/☐☐ (d d / m m m / y y)
					☐☐/☐☐☐/☐☐ (d d / m m m / y y)	☐☐/☐☐☐/☐☐ (d d / m m m / y y)

Route of Admin :
1 = Oral
2 = IV
3 = Sub. Cut.
4 = Topical
5 = Suppository
6 = Other (please specify)

Any other concurrent conditions?

Yes ☐ No ☐ (If yes, please specify below and continue on a separate sheet if necessary)

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Participant details

Initials: ☐☐☐

Subject ID No:

Date of Birth: ☐☐/☐☐☐/☐☐☐☐ (d d m m m y y y y)

Additional pages attached to this form: ☐☐

I confirm this is an SAE

PI Signature:

PI Name Printed:

Date: ☐☐/☐☐☐/☐☐ (d d m m m y y)

I confirm that this is an UNEXPECTED AND RELATED SAE ☐ Yes ☐ No *If no, please attach discussion with site & send the outcome in as Follow Up form*

CI Signature:

CI Name Printed:

Date: ☐☐/☐☐☐/☐☐ (d d m m m y y)

Co-ordinating office use only:

Date event received in Co-ordinating office? ☐☐/☐☐☐/☐☐ (d d m m m y y)

Co-ordinating Site Trial SAE Ref. No:

Date sae reported to Main REC: ☐☐/☐☐☐/☐☐ (d d m m m y y)

Reported to other PIs? ☐ Yes ☐ No

Co-ordinator Signature:

Co-ordinator Name Printed:

Date: ☐☐/☐☐☐/☐☐ (d d m m m y y)