

How to complete the outcome form

Completing the outcome form

- The Outcome Form should be completed at:
 - 28 days from randomisation OR
 - at prior death, discharge or transfer
- If transfer is soon after randomisation, a follow-up outcome should be obtained
- Days are counted from the date of randomisation (28 days = exactly 4 weeks) eg a patient randomised on 1 July: outcome due 29 July
- Use a paper form to capture the outcome data directly from the patient's medical records
- Please use permanent ink when completing the form

CRASH-3 OUTCOME FORM
 COMPLETE AT DISCHARGE FROM THE RANDOMISING HOSPITAL,
 DEATH IN HOSPITAL OR 28 DAYS AFTER INJURY, WHICHEVER OCCURS FIRST

At CRASH-3 9251/91

1. HOSPITAL (Hospital code) **000**

2. PATIENT a) BOX b) PACK c) INITIALS

3. OUTCOME

3.1 DEATH IN HOSPITAL

a) Date of death b) Time of death

c) Primary Cause of death (tick one option)

Head injury
 Bleeding
 Pulmonary embolism
 Stroke
 Myocardial infarction
 Multi organ failure
 Other/describe here (only one)

3.2 PATIENT ALIVE

a) Still in this hospital now (28 days after randomisation) - Date

b) Discharged to another hospital - Date of discharge

c) Discharged home - Date of discharge

3.3 IF ALIVE - DISABILITY RATING SCALE (tick one response for each box) - see overleaf for guidance

III EYE OPENING **IV COMMUNICATION ABILITY** **VI MOTOR RESPONSE** **V FEEDING** **VII TOILETING**

II GROOMING **IV LEVEL OF FUNCTIONING** **V EMPLOYABILITY**

3.4 IF ALIVE: Assessed by doctor/nurse/relative based on their knowledge of the patient, or patient if able (tick one response for each box)

SEE GUIDANCE OVERLEAF

4. MANAGEMENT

a) DAYS IN INTENSIVE CARE UNIT (if no ICU or not admitted to ICU, write '0' here) **2**

b) TYPE OF NEUROSURGICAL OPERATION

i) Haematomas evacuation **YES** **NO**

ii) Other **YES** **NO**

c) BLOOD LOSS DURING NEUROSURGICAL OPERATION

Estimated Volume (ml) **2000**

5. TRIAL TREATMENT

a) Loading dose given **YES** **NO**

b) Maintenance dose given **YES** **NO**

6. COMPLICATIONS (tick one option in every line)

Pulmonary embolism **YES** **NO**

Deep vein thrombosis **YES** **NO**

Stroke **YES** **NO**

Myocardial infarction **YES** **NO**

Renal failure **YES** **NO**

Sepsis **YES** **NO**

Seizure **YES** **NO**

Gastro intestinal bleeding **YES** **NO**

7. OTHER COMPLICATIONS **YES** **NO**

IF YES, REPORT AS PER PROTOCOL USING ADVERSE EVENT FORM

8. PERSON COMPLETING FORM

a) Name **Dr Tim Harris** b) Position **Principal Investigator**

c) Signature **Tim Harris** d) Date **30/05/2012**

Protocol Code: ISRCTN15088122 Outcome form version 1.0 dated 1 October 2011

Completing the outcome form

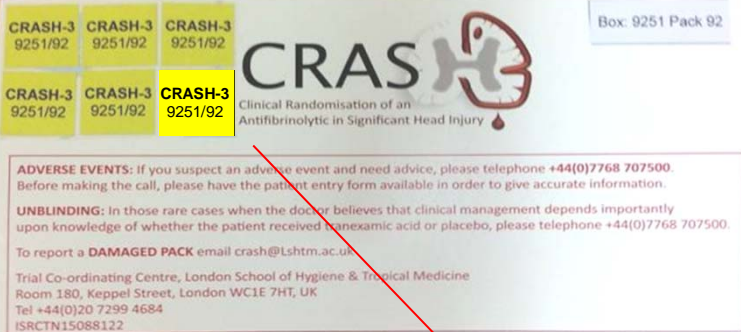
1. HOSPITAL (CODE)

Enter the trial ID number for your hospital – this is the 3-digit code on the contact sheet in your study file

2. PATIENT

(a+b) – There is space at the top of the form for the yellow sticker from the drug pack (the randomisation number). If you don't have the sticker please write the box/pack number clearly in the space provided.

(c) – Patient initials from the first name and last name eg Amara Kumara Star will be AS – if only one name is known enter that single initial.



CRASH-3 9251/92 CRASH-3 9251/92 CRASH-3 9251/92

CRASH-3 9251/92 CRASH-3 9251/92 CRASH-3 9251/92

Box: 9251 Pack 92

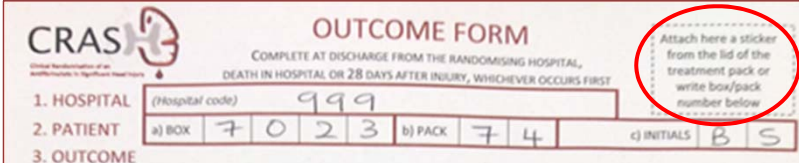
CRASH-3
Clinical Randomisation of an Antifibrinolytic in Significant Head Injury

ADVERSE EVENTS: If you suspect an adverse event and need advice, please telephone +44(0)7768 707500. Before making the call, please have the patient entry form available in order to give accurate information.

UNBLINDING: In those rare cases when the doctor believes that clinical management depends importantly upon knowledge of whether the patient received tranexamic acid or placebo, please telephone +44(0)7768 707500.

To report a DAMAGED PACK email crash@lshtm.ac.uk

Trial Co-ordinating Centre, London School of Hygiene & Tropical Medicine
Room 180, Keppel Street, London WC1E 7HT, UK
Tel +44(0)20 7299 4684
ISRCTN15088122



CRASH-3 OUTCOME FORM

COMPLETE AT DISCHARGE FROM THE RANDOMISING HOSPITAL,
DEATH IN HOSPITAL OR 28 DAYS AFTER INJURY, WHICHEVER OCCURS FIRST

1. HOSPITAL (Hospital code) 999

2. PATIENT a) BOX 7 0 2 3 b) PACK 7 4 c) INITIALS B S

3. OUTCOME

Attach here a sticker from the lid of the treatment pack or write box/pack number below

Section 3.1 – Outcome death in hospital

Only complete if the patient dies

- a) Enter date of death in the format DD/MM/YYYY eg 19/07/2012
- b) Enter the time of death in the format hh/mm eg 23/43
- c) Indicate (with a tick ✓) the primary cause of death – if more than one cause, please enter **ONLY the main cause**

3.1 DEATH IN HOSPITAL				
a) Date of death			b) Time of death	
19 <small>DAY (DD)</small>	07 <small>MONTH (MM)</small>	2012 <small>YEAR (YYYY)</small>	23 <small>HOUR (HH)</small>	43 <small>MIN (MM)</small>
c) Primary Cause of death <small>(tick one option)</small>				
<input type="checkbox"/> Head injury				
<input type="checkbox"/> Bleeding				
<input type="checkbox"/> Pulmonary embolism				
<input type="checkbox"/> Stroke				
<input type="checkbox"/> Myocardial Infarction				
<input type="checkbox"/> Multi organ failure				
<input checked="" type="checkbox"/> Other/describe here (only one) <u>RENAL FAILURE</u>				

Section 3.2 – Outcome patient alive

Only complete if the patient is alive

3.2 PATIENT ALIVE		
a) Still in this hospital now (28 days after randomisation) – Date		
28 <small>DAY (DD)</small>	11 <small>MONTH (MM)</small>	2012 <small>YEAR (YYYY)</small>
b) Discharged to another hospital – Date of discharge		
<small>DAY (DD)</small>	<small>MONTH (MM)</small>	<small>YEAR (YYYY)</small>
c) Discharged home – Date of discharge		
<small>DAY (DD)</small>	<small>MONTH (MM)</small>	<small>YEAR (YYYY)</small>

Enter the date of discharge, transfer, or still in hospital at 28 days in the format DD/MM/YYYY eg 28/11/2012

Only one line to be completed

Section 3.3 – Status if alive

Complete the DISABILITY RATING SCALE questions **a–h** following the guidance on reverse of the outcome form.

See HOW TO COMPLETE THE DSR presentation for guidance on this section

3.3 IF ALIVE – DISABILITY RATING SCALE <i>(tick one response for each box) – see overleaf for guidance</i>				
a) EYE OPENING <input type="checkbox"/> Spontaneous <input checked="" type="checkbox"/> To Speech <input type="checkbox"/> To Pain <input type="checkbox"/> None	b) COMMUNICATION ABILITY <input type="checkbox"/> Oriented <input checked="" type="checkbox"/> Confused <input type="checkbox"/> Inappropriate <input type="checkbox"/> Incomprehensible <input type="checkbox"/> None	c) MOTOR RESPONSE <input type="checkbox"/> Obeying <input checked="" type="checkbox"/> Localizing <input type="checkbox"/> Withdrawing <input type="checkbox"/> Flexing <input type="checkbox"/> Extending <input type="checkbox"/> None	d) FEEDING <i>(cognitive ability only)</i> <input type="checkbox"/> Complete <input checked="" type="checkbox"/> Partial <input type="checkbox"/> Minimal <input type="checkbox"/> None	e) TOILETING <i>(cognitive ability only)</i> <input type="checkbox"/> Complete <input checked="" type="checkbox"/> Partial <input type="checkbox"/> Minimal <input type="checkbox"/> None
f) GROOMING <i>(cognitive ability only)</i> <input type="checkbox"/> Complete <input checked="" type="checkbox"/> Partial <input type="checkbox"/> Minimal <input type="checkbox"/> None	g) LEVEL OF FUNCTIONING <i>(physical, mental, emotional or social function)</i> <input type="checkbox"/> Completely independent <input type="checkbox"/> Independent in special environment <input type="checkbox"/> Mildly dependent – limited assistance <input checked="" type="checkbox"/> Moderately dependent – moderate assistance <input type="checkbox"/> Markedly dependent – assist all major activities, all times <input type="checkbox"/> Totally dependent – 24-hour nursing care		h) EMPLOYABILITY <i>(as a full time worker, homemaker, or student)</i> <input type="checkbox"/> Not restricted <input type="checkbox"/> Selected jobs, competitive <input type="checkbox"/> Sheltered workshop, non-competitive <input checked="" type="checkbox"/> Not employable	

You must tick one box for response to each of the eight questions

Section 3.4 – Status if alive

Complete the Assessment questions **a–f** following the guidance on reverse of the outcome form.

3.4 IF ALIVE: Assessed by doctor/nurse/relative based on their knowledge of the patient, or patient if able (tick one response for each box)
SEE GUIDANCE OVERLEAF

a) WALKING	b) WASHING / DRESSING	c) PAIN / DISCOMFORT	d) ANXIETY / DEPRESSION	e) AGITATION / AGGRESSION	f) FATIGUE
<input type="checkbox"/> No problems	<input checked="" type="checkbox"/> No problems	<input type="checkbox"/> None	<input checked="" type="checkbox"/> None	<input checked="" type="checkbox"/> None	<input type="checkbox"/> None
<input checked="" type="checkbox"/> Some problems	<input type="checkbox"/> Some problems	<input checked="" type="checkbox"/> Moderate	<input type="checkbox"/> Moderate	<input type="checkbox"/> Moderate	<input checked="" type="checkbox"/> Moderate
<input type="checkbox"/> Confined to bed	<input type="checkbox"/> Unable	<input type="checkbox"/> Extreme	<input type="checkbox"/> Extreme	<input type="checkbox"/> Extreme	<input type="checkbox"/> Extreme

You must tick one box for response to each of the six questions

Section 4 – Management

IT IS ESSENTIAL THAT ALL QUESTIONS ARE ANSWERED

4. MANAGEMENT		
a) DAYS IN INTENSIVE CARE UNIT <i>(if no ICU or not admitted to ICU, write '0' here)</i>	5	
b) TYPE OF NEUROSURGICAL OPERATION		
i) Haematoma evacuation	<input checked="" type="radio"/> YES	<input type="radio"/> NO
ii) Other	<input type="radio"/> YES	<input checked="" type="radio"/> NO
c) BLOOD LOSS DURING NEUROSURGICAL OPERATION		
Estimated Volume (ml)	130	

4a) Please write **0** if there is no ICU department or if the patient was not admitted to ICU – part day counts as 1

4b) Please ensure you circle one choice on **EACH LINE** – do not leave any without circling either YES or NO

(the estimated blood loss volume refers only to the volume lost during the first neurosurgical operation after randomisation)

Section 5 – Trial treatment

Please ensure you circle one choice on EACH LINE

5. TRIAL TREATMENT		
a) Loading dose given	<input checked="" type="radio"/> YES	<input type="radio"/> NO
b) Maintenance dose given	<input type="radio"/> YES	<input checked="" type="radio"/> NO

- You must circle one choice for EACH dose – do not leave blank
- If either dose is **only partially given** it must be entered here as **NO**
- Only a fully administered dose will be **YES**

Section 6 – Complications

Section 7 – Other complications

6. COMPLICATIONS		
<i>(circle one option on every line)</i>		
Pulmonary embolism	YES	<input checked="" type="radio"/> NO
Deep vein thrombosis	YES	<input checked="" type="radio"/> NO
Stroke	YES	<input checked="" type="radio"/> NO
Myocardial infarction	YES	<input checked="" type="radio"/> NO
Renal failure	<input checked="" type="radio"/> YES	NO
Sepsis	YES	<input checked="" type="radio"/> NO
Seizure	<input checked="" type="radio"/> YES	NO
Gastro intestinal bleeding	YES	<input checked="" type="radio"/> NO

- All complications listed must be a confirmed diagnosis
- You must circle either YES or NO for ALL complications
- Any complication not listed here but fulfils the Adverse Event criteria (see Protocol page 13) should be reported using the 'Adverse Event Reporting Form'

Section 8 – Person completing the form

*This section must be completed in full –
it is a declaration that the data is valid*

8. PERSON COMPLETING FORM		THE PRINCIPAL INVESTIGATOR IS RESPONSIBLE FOR ALL DATA SUBMITTED	
a) Name	ROBIN HOOD	b) Position	CONSULTANT
c) Signature	<i>R Hood</i>	d) Date	4/6/12

Corrections

If you enter an incorrect value on the form:

- cross out the incorrect value so it is still visible
- enter the correct value alongside
- enter the date and your initials next to each change

EXAMPLES

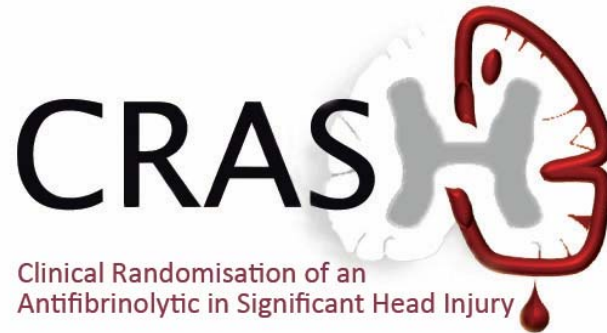
3.2 PATIENT ALIVE

a) Still in this hospital now (28 days after randomisation) - Date		
DAY (DD)	MONTH (MM)	YEAR (YYYY)
b) Discharged to another hospital - Date of discharge		
DAY (DD)	MONTH (MM)	YEAR (YYYY)
30 29 RH	04	2012
c) Discharged home - Date of discharge		
DAY (DD)	MONTH (MM)	YEAR (YYYY)
30/4/12		

e) AGITATION / AGGRESSION	f) FATIGUE
<input checked="" type="checkbox"/> None RH	<input type="checkbox"/> None
<input checked="" type="checkbox"/> Moderate 30/4/12	<input checked="" type="checkbox"/> Moderate
<input type="checkbox"/> Extreme	<input type="checkbox"/> Extreme

**Please store original forms in Section 16
of your Study File**

**SEE SEPARATE GUIDANCE ABOUT HOW
TO SEND THE DATA FORMS TO THE TCC**



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