

STASH CRF FORM (CRF2)

Any deterioration? Yes
 No

CENTRE NAME.....
 PATIENT INITIALS.....
 STUDY TREATMENT NUMBER.....

Please complete in block capitals and in black ink

CLINICAL DETERIORATION

***IF YES PLEASE ALSO COMPLETE ADVERSE EVENT (AESI) SHEET- CRF5**

DELAYED ISCHAEMIA - SUSPECTED

Onset date / /

	yes	no
Drop in GCS at least 2 pt	<input type="checkbox"/>	<input type="checkbox"/>
Focal deficit	<input type="checkbox"/>	<input type="checkbox"/>
Proven radiological ischaemic infarct*	<input type="checkbox"/>	<input type="checkbox"/>
Is DID suspected?	<input type="checkbox"/>	<input type="checkbox"/>
Is DID confirmed?	<input type="checkbox"/>	<input type="checkbox"/>

OTHER CAUSES OF CLINICAL DETERIORATION

	yes	no
Sepsis	<input type="checkbox"/>	<input type="checkbox"/>
Epilepsy	<input type="checkbox"/>	<input type="checkbox"/>
Hypoxia	<input type="checkbox"/>	<input type="checkbox"/>
*Rebleed	<input type="checkbox"/>	<input type="checkbox"/>
Hydrocephalus (req drainage)	<input type="checkbox"/>	<input type="checkbox"/>
Other.....		

SUSPECTED STATIN RELATED DETERIORATION

*Raised LFTs or CK	<input type="checkbox"/>	<input type="checkbox"/>
*Interstitial lung disease	<input type="checkbox"/>	<input type="checkbox"/>
*Rhabdomyolysis	<input type="checkbox"/>	<input type="checkbox"/>
Other.....		

Extended hypervolaemic therapy
 yes no days

Inotropic support
 yes no days

Angioplasty
 yes no days

THERAPY

Intraarterial papavarine /nimodipine
 yes no days

ITU/HDU stay
 yes no days

Steroids
 yes no days

STASH CRF FORM (CRF3)

CENTRE NAME.....
PATIENT INITIALS.....
STUDY TREATMENT NUMBER.....

Please complete in block capitals and in black ink

Sepsis? Yes
 No

SEPSIS

Temperature (>39°C or <36°C) yes no

Heart rate (>90 beats/min) yes no

Respiratory rate (>20 breaths/min or PaCO₂<4.3kPa) yes no

WBC (> 12,000cells/mm³, <4,000cells/mm³ or >10% immature (band forms)) yes no

Has sepsis been confirmed (e.g. positive culture)?
yes no

Please qualify (e.g. known or suspected site of infection)

What are the consequences/treatment of sepsis?

Prolonged invasive ventilation for sepsis yes no
 days onset date / /

Blood products for sepsis yes no
 days onset date / /

Renal replacement therapy for sepsis yes no
 days onset date / /

Inotropes for sepsis yes no
 days onset date / /

Other (please qualify)
 days onset date / /

STASH CRF FORM (CRF4)

CENTRE NAME.....
 PATIENT INITIALS.....
 STUDY TREATMENT NUMBER.....

Please complete in block capitals and in black ink

Please complete all boxes

LABORATORY RESULTS

	Date	CRP	*Bili	*ALT	*ALP	*CK	*albumin	Total chole	LDL	HDL	TG
Baseline - day 1 (day of first dose)											
Day 9 - 12											

	Na	K	glucose	Mg
Baseline (Day 1)				
Day 9 - 12				

Hct	Hb	WBC	Plts

***Abnormal CK or LFTs that are >3 times upper limit of normal - report as an adverse event and also complete CRF5**

Mild 3 – 5 times upper limit of normal

Moderate 5 – 7 times upper limit of normal

Severe >7 times upper limit of normal

No other abnormal blood results to be reported as an adverse event

PLEASE PRINT OUT A PAPER COPY OF THE LABORATORY BLOOD RESULTS, ANONYMISE AND RETAIN WITH THE CRF

Investigator's signature..... Date.....

Please photocopy sheet if necessary

STASH CRF FORM (CRF5)
 CENTRE NAME.....
 PATIENT INITIALS.....
 STUDY TREATMENT NUMBER.....

Please complete in block capitals and in black ink

Please tick box if there were NO adverse events of special interest (AESIs)

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ADVERSE EVENTS (AESIs) & ADVERSE REACTIONS

Adverse Event (AESI) or Reaction (AR) (one event/line only)	Onset date	Resolved/end date	†Severity	††Causality	†††Action taken	††††Outcome	*? SAE (Y/N)
	□ □ / □ □ □ / □ □	□ □ / □ □ □ / □ □					
	□ □ / □ □ □ / □ □	□ □ / □ □ □ / □ □					
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	□ □ / □ □ □ / □ □	□ □ / □ □ □ / □ □					

†Severity 1 = mild 2 = moderate 3 = severe	††Causality (to study drug) 1 = unrelated 2 = unlikely 3 = possibly related 4 = probably related	†††Action taken 1 = none 2 = dose interrupted 3 = study drug discontinued	††††Outcome 1 = recovered 2 = recovered with sequelae 3 = not recovered 4 = lost to follow up 5 = fatal	*If considered to be an SAE, please also complete an SAE form and fax to Study Coordinating Centre WITHIN 24 HRS OF BECOMING AWARE
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Investigator's signature..... Date.....

STASH CRF FORM (CRF6)

CENTRE NAME.....
PATIENT INITIALS.....
STUDY TREATMENT NUMBER.....

Please complete in block capitals and in black ink

STUDY MEDICATION

Start date of medication	<input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/>
Stop date of medication	<input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/>
Number of tablets taken	<input type="text"/>
Number of tablets returned to Pharmacy	<input type="text"/>
Date of any missed medications	<input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/>
	<p style="text-align: right;">Cause(s) if known</p> <div style="border: 1px solid black; height: 150px; width: 100%;"></div>

STASH CRF FORM (CRF7)

CENTRE NAME.....
PATIENT INITIALS.....
STUDY TREATMENT NUMBER.....

Please complete in block capitals and in black ink

DISCHARGE OUTCOME

Discharged? yes no

Date of discharge / /

GCS on discharge E V M

Discharged to please tick

 Non-neurosurgical ward

 Rehabilitation unit

 Home

 Other.....

Died? yes no

Date of death / /

Cause of death

 Initial SAH

 DID

 Rebleed

 Sepsis

 Other, please state below

Modified Rankin Disability Score at discharge

date / /

- 0 no symptoms at all
- 1 no significant disability despite symptoms; able to carry out all usual duties and activities
- 2 slight disability: unable to carry out all previous activities but able to look after own affairs without assistance
- 3 moderate disability; requiring some help, but able to walk without assistance
- 4 moderate to severe disability; unable to walk without assistance, and unable to attend to own bodily needs without assistance
- 5 severe disability; bedridden, incontinent, requiring constant nursing care and attention
- 6 death

Name of person completing form _____

Signature _____ Date _____

PI Signature-----Date-----