

STASH CRF FORM (CRF1)

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

Please complete in block capitals and in black ink

INVESTIGATIONS / PERI-OPERATIVE EVENTS

Angiogram type (please tick if done)
MRA CTA DSA

Imaging date
□ □ / □ □ □ □ / □ □ □ □

Location of aneurysm please tick

Acomm	<input type="checkbox"/>
Pcomm	<input type="checkbox"/>
ICA	<input type="checkbox"/>
MCA	<input type="checkbox"/>
Post circulation	<input type="checkbox"/>
Other	<input type="checkbox"/>
 AVM	<input type="checkbox"/>
Other	<input type="checkbox"/>

Aneurysm treatment date
□ □ / □ □ □ □ / □ □ □ □

Clipped? yes no

Coiled? yes no

Immediate (<6hrs) procedural problems/deficits?
yes no

Date □ □ / □ □ □ □ / □ □ □ □

Please state nature and suspected cause of deterioration

Intra-operative bleed

Uncontrolled intra-operative cerebral swelling

Cerebral ischaemic episode due to:

Major vessel occlusion

Thrombo-embolic event

Other (please specify)

.....

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STASH CRF FORM (CRF2)

Any deterioration? Yes
 No

CENTRE NAME.....
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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.....
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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.....
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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)
	□ □ / □ □ □ / □ □	□ □ / □ □ □ / □ □					
	□ □ / □ □ □ / □ □	□ □ / □ □ □ / □ □					
	□ □ / □ □ □ / □ □	□ □ / □ □ □ / □ □					
	□ □ / □ □ □ / □ □	□ □ / □ □ □ / □ □					
	□ □ / □ □ □ / □ □	□ □ / □ □ □ / □ □					
	□ □ / □ □ □ / □ □	□ □ / □ □ □ / □ □					

†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.....
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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.....
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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-----