OUTCOME

Complete at discharge from the randomising hospital, death in hospital or 28 days after randomisation, whichever occurs first

Attach treatment pack sticker or write box/pack number: ☐☐☐☐/☐☐

1. HOSPITAL

a) Country	
b) Hospital code	

2. PATIENT DETAILS

a) Initials	*first*	*last*
b) Age at entry		
c) Written consent obtained from patient or representative?	YES	NO
d) If no written consent, give reason		

3. PATIENT STATUS

3.1 Death in hospital *(if yes complete below – if no complete 3.2)*

a) Date of death	*dd*	*mm*	*yyyy*
b) Time of death *(24-hr clock)*	*hours*	*minutes*	

c) Main cause of death *(tick one option only)*

☐ Haemorrhage ☐ Malignancy
☐ Myocardial infarction ☐ Pneumonia
☐ Stroke ☐ Pulmonary embolism
☐ Other *(describe, 1 diagnosis only)*

_____

3.2 Patient alive *(if yes complete **one** section below – if no complete 3.1)*

a) Discharged from hospital? *(Date)*	*dd*	*mm*	*yyyy*
b) Still in hospital at day 28? *(Date)*	*dd*	*mm*	*yyyy*

4. PROCEDURES *(circle one option on each line)*

a) Diagnostic endoscopic procedure	YES	NO
b) Therapeutic endoscopic procedure	YES	NO
c) Diagnostic radiological procedure	YES	NO
d) Therapeutic radiological procedure	YES	NO
e) Surgical intervention	YES	NO

5. PRIMARY CAUSE OF BLEED *(tick one option only)*

UPPER GI BLEED	LOWER GI BLEED
☐ Erosion or peptic ulcer	☐ Diverticular disease
☐ Varices	☐ Colitis
☐ Vascular lesion	☐ Vascular lesion
☐ Malignancy	☐ Malignancy
☐ Other/unknown	☐ Infection
	☐ Other/unknown

6. TRIAL TREATMENT *(only circle YES if complete dose given)*

a) Loading dose given	YES	NO
b) Maintenance dose given	YES	NO

7. OTHER TREATMENTS *(circle one option on each line)*

a) Helicobacter pylori eradication	YES	NO
b) H2 receptor antagonists	YES	NO
c) Proton pump inhibitors	YES	NO
d) Vasopressin / analogue	YES	NO
e) Antibiotics for variceal bleeding	YES	NO
f) Antifibrinolytics	YES	NO

8. BLOOD PRODUCTS TRANSFUSION *(if none enter 0)*

a) Were blood products transfused?	YES	NO
b) Units whole blood/red cells *(part unit = 1 unit)*	*units*	
c) Frozen plasma *(part unit = 1 unit)*	*units*	
d) Platelets *(part unit = 1 unit)*	*units*	

9. MANAGEMENT *(if none enter 0)*

a) Days in Intensive Care Unit (ICU)	*days*
b) Days in High Dependency Unit (HDU)	*days*

10. COMPLICATIONS *(circle one option on each line)*

a) Re-bleeding (up to point of outcome)		YES	NO
i) If yes, number of re-bleeding episodes			
ii) Date of episode 1	*dd*	*mm*	*yyyy*
Additional episodes to be recorded on reverse			
b) Deep vein thrombosis		YES	NO
c) Pulmonary embolism		YES	NO
d) Stroke		YES	NO
e) Myocardial infarction		YES	NO
f) Other significant cardiac event		YES	NO
g) Sepsis		YES	NO
h) Pneumonia		YES	NO
i) Respiratory failure		YES	NO
j) Liver failure		YES	NO
k) Renal failure		YES	NO
l) Seizures		YES	NO

Any complications not listed above – please report as per protocol using an Adverse Event Reporting form.

11. PATIENT'S SELF CARE CAPACITY

(circle one option on each line)	INDEPENDENT?	
a) Bathing *(sponge bath, tub bath, or shower) – Receives either no assistance or assistance in bathing only one part of body*	YES	NO
b) Dressing *– Gets clothed and dressed without assistance except for tying shoes*	YES	NO
c) Toileting *– Goes to toilet room, uses toilet, arranges clothes, and returns without assistance (may use cane or walker for support and bedpan/urinal at night)*	YES	NO
d) Transferring *– Moves in and out of bed and chair without assistance (may use cane or walker)*	YES	NO
e) Continence *– Controls bowel and bladder completely by self (without occasional 'accidents')*	YES	NO
f) Feeding *– Feeds self without assistance (except for help with cutting meat or buttering bread)*	YES	NO

UK ONLY – PATIENT IDENTIFIERS

a) Name	*first name*	*family name*	
b) Date of birth	*dd*	*mm*	*yyyy*
c) Post code			
d) NHS number			

12. PERSON COMPLETING FORM *(PI is responsible for data submitted)*

a) Name	*first name*	*last name*
b) Position		
c) Signature		
d) Date	*dd*	*mm* *yyyy*

ADDITIONAL RE-BLEEDING INFORMATION

Q.10 a ii) Date of re-bleed episodes cont. *(please report all ADDITIONAL episodes of re-bleeding that are NOT captured on page 1)*

EPISODE NUMBER	DATE		
2	dd	mm	yyyy
3	dd	mm	yyyy
4	dd	mm	yyyy
5	dd	mm	yyyy
6	dd	mm	yyyy
7	dd	mm	yyyy
8	dd	mm	yyyy
9	dd	mm	yyyy
10	dd	mm	yyyy
11	dd	mm	yyyy
12	dd	mm	yyyy
13	dd	mm	yyyy
14	dd	mm	yyyy
15	dd	mm	yyyy

DETAILED GUIDANCE ABOUT COMPLETING THIS FORM CAN BE FOUND IN YOUR INVESTIGATORS STUDY FILE

AFTER COMPLETING THIS PAPER FORM, YOU CAN:

- Enter these data directly into the trial database. For username and password, please contact **haltit.data@Lshtm.ac.uk**
- Send as a secure scanned document by email to **haltit.data@Lshtm.ac.uk** or upload a scanned copy at **http://ctu-files.Lshtm.ac.uk**.
- Fax to **+44 20 7299 4663**

STORE THIS ORIGINAL FORM IN YOUR SITE FILE