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Roberts, I; Coats, T; Edwards, P; Gilmore, I; Jairath, V; Ker, K; Manno, D; Shakur, H; Stanworth, S; Veitch, A; (2014) HALT-IT - tranexamic acid for the treatment of gastrointestinal bleeding: study protocol for a randomised controlled trial. *Trials*, 15 (1). p. 450. ISSN 1745-6215 DOI: <https://doi.org/10.1186/1745-6215-15-450>

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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)	<input type="checkbox"/> Haemorrhage <input type="checkbox"/> Malignancy <input type="checkbox"/> Myocardial infarction <input type="checkbox"/> Pneumonia <input type="checkbox"/> Stroke <input type="checkbox"/> Pulmonary embolism <input type="checkbox"/> 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
<input type="checkbox"/> Erosion or peptic ulcer	<input type="checkbox"/> Diverticular disease
<input type="checkbox"/> Varices	<input type="checkbox"/> Colitis
<input type="checkbox"/> Vascular lesion	<input type="checkbox"/> Vascular lesion
<input type="checkbox"/> Malignancy	<input type="checkbox"/> Malignancy
<input type="checkbox"/> Other/unknown	<input type="checkbox"/> Infection
	<input type="checkbox"/> 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	YES	NO
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

SEE GUIDANCE NOTES ON REVERSE

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@Lshmt.ac.uk**
- ❖ Send as a secure scanned document by email to **haltit.data@Lshmt.ac.uk** or upload a scanned copy at **<http://ctu-files.Lshmt.ac.uk>**.
- ❖ Fax to **+44 20 7299 4663**

STORE THIS ORIGINAL FORM IN YOUR SITE FILE