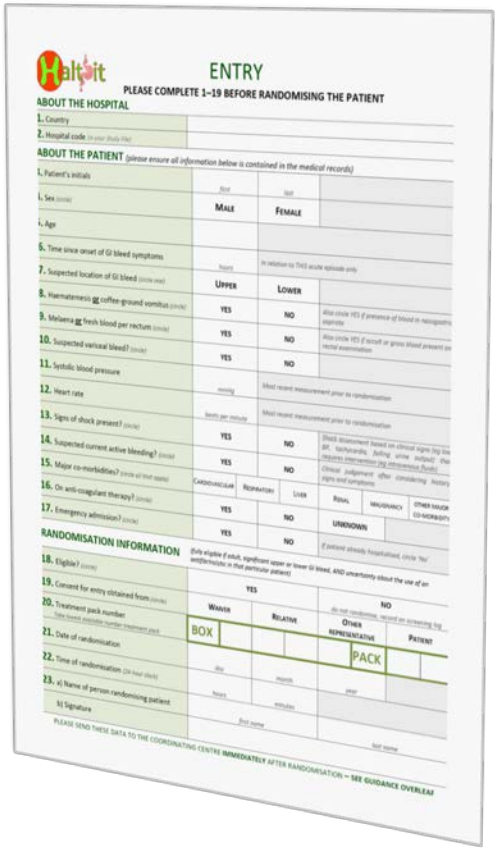
Haemorrhage alleviation with tranexamic acid - Intestinal system

HOW TO COMPLETE THE ENTRY FORM

How to complete the entry form

- Use the paper form to collect entry information
- Ensure that the information is recorded in the medical records – a label is provided for this
- Forms are sent with the drug box with spare forms in the Study File (section 15), CD and on the website
- Please use permanent ink
- Questions 1–18 must be completed to assess eligibility before starting the consent procedure
- When consent completed fill in the remaining fields


ENTRY

PLEASE COMPLETE 1–19 BEFORE RANDOMISING THE PATIENT

ABOUT THE HOSPITAL

1. Country

2. Hospital code

ABOUT THE PATIENT (please ensure all information below is contained in the medical records)

1. Patient's initials

3. Sex: MALE / FEMALE

4. Age

5. Time since onset of GI bleed symptoms

7. Suspected location of GI bleed: UPPER / LOWER

8. Haematemesis or coffee-ground vomitus: YES / NO

9. Melaena or fresh blood per rectum: YES / NO

10. Suspected variceal bleed? YES / NO

11. Systolic blood pressure

12. Heart rate

13. Signs of shock present? YES / NO

14. Suspected current active bleeding? YES / NO

15. Major co-morbidities? CARDIOVASCULAR / RESPIRATORY / LIVER / RENAL / MALIGNANCY / OTHER MAJOR CO-MORBIDITY

16. On anti-coagulant therapy? YES / NO / UNKNOWN

17. Emergency admission? YES / NO

RANDOMISATION INFORMATION

18. Eligible? YES / NO

19. Consent for entry obtained from: WAIVER / RELATIVE / OTHER REPRESENTATIVE / PATIENT

20. Treatment pack number: BOX / PACK

21. Date of randomisation

22. Time of randomisation

23. a) Name of person randomising patient

b) Signature

PLEASE SEND THESE DATA TO THE COORDINATING CENTRE IMMEDIATELY AFTER RANDOMISATION – SEE GUIDANCE OVERLEAF

ALL fields must be completed for all randomised patients

Sections 1–2 About your hospital

Halt it

ENTRY

PLEASE COMPLETE 1–19 BEFORE RANDOMISING THE PATIENT

ABOUT THE HOSPITAL

1. Country	ITALY
2. Hospital code *(in your Study File)*	999

1. Country

- Write the name of your country in full

2. Hospital Code

- Enter the ID code for your site – the 3-digit number on the contact page of your Study File

Sections 3–5 About the patient

ABOUT THE PATIENT *(please ensure all information below is contained in the medical records)*			
3. Patient's initials	B *first*	S *last*	
4. Sex *(circle)*	(MALE)	FEMALE	
5. Age	60		

3. Patient initials

- Enter the patient's initials in the format FIRST name and LAST name
  eg Bilbo Frodo Samwell = **BS**
- If only one name is known enter that initial only
- If name is unknown because the patient has not been identified, use your hospital standard procedure (eg NK = not known)

4. Sex

- Specify if patient is MALE or FEMALE

DO NOT RANDOMISE IF PATIENT DOES NOT MEET THE ADULT AGE REQUIREMENT FOR YOUR COUNTRY

5. Age

- Enter age in years
- If unknown, please enter *approximate* age in years

Sections 6–7 GI bleeding time and suspected location

6. Time since onset of GI bleed symptoms	3 *hours*	*In relation to THIS acute episode only*	
7. Suspected location of GI bleed *(circle one)*	(UPPER)	LOWER	

6. Time since onset of GI bleeding

- Please provide the best estimate in hours from patient's history
- Only in relation to the acute episode

7. Suspected location of GI bleed

- Please provide the suspected location of GI bleeding according to clinical symptoms and patient's history

Sections 8–10 GI bleeding

8. Haematemesis **or** coffee-ground vomitus *(circle)*	YES	NO	*Also circle YES if presence of blood in nasogastric aspirate*
9. Melaena **or** fresh blood per rectum *(circle)*	YES	NO	*Also circle YES if occult or gross blood present on rectal examination*
10. Suspected variceal bleed? *(circle)*	YES	NO	

8. Haematemesis or coffee-ground vomitus

- If presence of blood in nasogastric aspirate, please circle YES

9. Melaena or fresh blood per rectum

- If occult or gross blood present on rectal examination, please circle YES

10. Suspected variceal bleed?

- This is based on a clinical judgment, endoscopy is not needed to answer this question

Please answer according to clinical signs and symptoms and patient's history

Sections 11–13 Patient's condition

11. Systolic blood pressure	88 mmHg	*Most recent measurement prior to randomisation*	
12. Heart rate	102 beats per minute	*Most recent measurement prior to randomisation*	
13. Signs of shock present? *(circle)*	(YES)	NO	*Shock assessment based on clinical signs (eg low BP, tachycardia, falling urine output) that requires intervention (eg intravenous fluids)*

11. Systolic blood pressure

- in mmHg

12. Heart rate

- in beats per minute

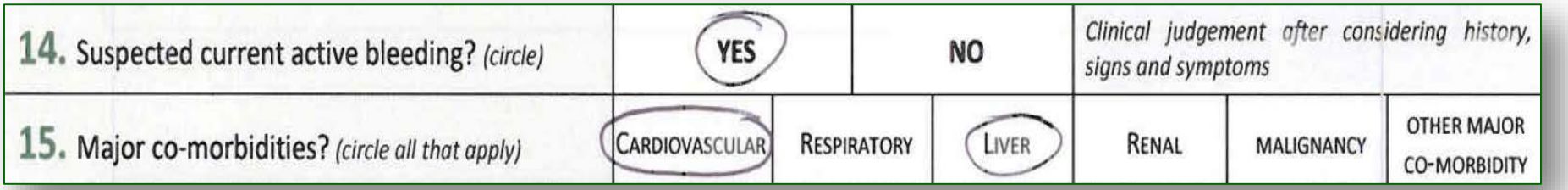
Provide most recent measurement prior to randomisation

Enter a value of '1' if unrecordable or '000' if value is missing – any missing value will require an explanation

13. Signs of shock present?

- Based on clinical signs (i.e. low BP, tachycardia, falling urine output) that require intervention (i.e. intravenous fluids)

Sections 14–15



14. Suspected current active bleeding? *(circle)*	YES		NO	*Clinical judgement after considering history, signs and symptoms*		
15. Major co-morbidities? *(circle all that apply)*	CARDIOVASCULAR	RESPIRATORY	LIVER	RENAL	MALIGNANCY	OTHER MAJOR CO-MORBIDITY

14. Suspected current active bleeding?

- Use clinical judgment – considering history, signs and symptoms

15. Major co-morbidities?

- Consider clinical history
- Circle all the co-morbidities present

Sections 16–17

16. On anti-coagulant therapy? *(circle)*	YES	(NO)	UNKNOWN	
17. Emergency admission? *(circle)*	(YES)	NO	*If patient already hospitalised, circle 'No'*	

16. On anti-coagulant therapy?

- Consider clinical history
- Record "unknown" if no information available

17. Emergency admission?

- If patient already hospitalised, circle "No"

Section 18 Randomisation

RANDOMISATION INFORMATION	*(fully eligible if adult, significant upper or lower GI bleed, AND uncertainty about the use of an antifibrInolytic in that particular patient)*	
18. Eligible? *(circle)*	YES	**NO** *do not randomise, record on screening log*

Eligible?

- Adults with significant upper or lower GI bleeding
- The diagnosis of 'significant' bleeding is clinical; patient may have hypotension and tachycardia and may need transfusion, urgent endoscopy or surgery
- Clinician is 'uncertain' as to whether or not to use tranexamic acid in that patient

YES–patient fulfils all the above eligibility criteria; consent process has been followed

- **RANDOMISE** – get lowest available numbered treatment pack and follow instructions on it
- Record on Randomisation Log and Drug Accountability Log
- Submit entry form data to TCC within 24 hours

NO – patient does not fulfil all eligibility criteria – **DO NOT RANDOMISE**

- Record on Screening Log
- If entry form used to assess eligibility, file in Study file Section 15

Section 19 Consent process

19. Consent for entry obtained from

- Only record the consent process used **prior to randomisation** i.e. do not record in this section the follow-up consent procedure after the emergency is over.
- **NOTE: if patient or relative AGREEMENT is given – this is recorded as a WAIVER**

Sections 20–22 Randomisation details

20. Treatment pack number *Take lowest available number treatment pack*	BOX	9	2	5	1	PACK	9	1
21. Date of randomisation	15 *day*		05 *month*		2013 *year*			
22. Time of randomisation *(24-hour clock)*	11 *hours*		20 *minutes*					

20. Treatment pack number

- Write box (4 digits) and pack (2 digits) number from treatment pack

21. Date of randomisation

- Enter in format day (DD) month (MM) year (YYYY)

22. Time of randomisation

- Enter in format hours (HH) minutes (MM)
- Use 24-hour clock format i.e. 6pm = 18:00
- Midnight is designated as 00:00 of the following day
  i.e. randomised on 25/05/2013 at midnight = 26/01/2013 at 00:00

Section 23 Randomisation declaration

23. a) Name of person randomising patient	LEONARDO *first name*	DA VINCI *last name*
b) Signature	Leonardo Da Vinci	

23. a) Name of person randomising

- Write your name in full – print clearly

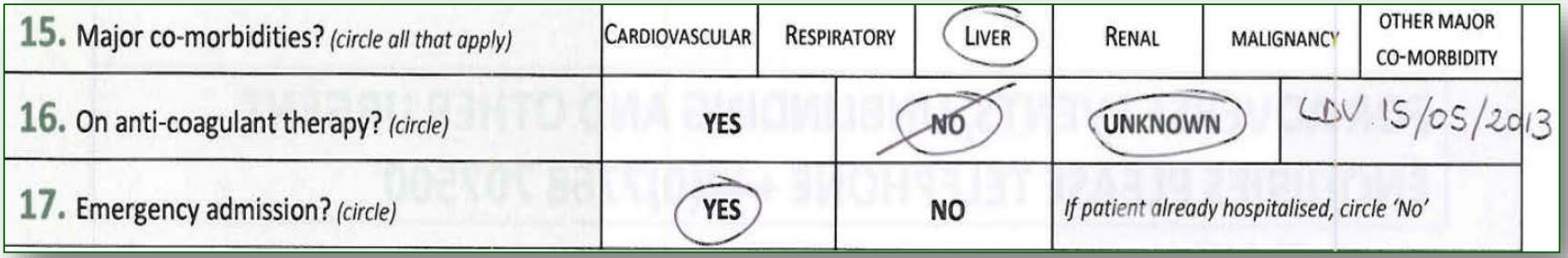
23. b) Signature

- Sign the form – to confirm the data on the form

How to make 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
- date and initial **each** change



15. Major co-morbidities? *(circle all that apply)*	CARDIOVASCULAR	RESPIRATORY	LIVER	RENAL	MALIGNANCY	OTHER MAJOR CO-MORBIDITY	
16. On anti-coagulant therapy? *(circle)*	YES	NO	UNKNOWN	LDV 15/05/2013			
17. Emergency admission? *(circle)*	YES	NO	*If patient already hospitalised, circle 'No'*				

Please store original forms in Study file Section 15

SEE SEPARATE GUIDANCE ON HOW TO SEND DATA TO THE TCC

Give a copy of the completed entry forms to the person responsible for completing the outcome forms at your hospital

JOIN THE GLOBAL COLLABORATION

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