



The Threshold for Platelets study: A prospective randomised trial to define the platelet count below which critically ill patients should receive a platelet transfusion prior to an invasive procedure

**All Site Meeting - 20 February 2023**

IRAS ID: 312405  
REC Ref: 22/SC/0186  
Funding: NIHR HTA (131822)

NIHR CPMS ID: 53274  
ISRCTN Registry: ISRCTN79371664  
Sponsor: University of Oxford

Chief Investigator: Prof Peter Watkinson

## Agenda

- Trial update
- Screening log reminders
- Screening scenario
- Screening log update
- Questions/site discussion

# Trial Update

- Open sites: **27**
- Recruitment to date: **39**
- Recruitment in February so far: **3**

	Site name	Date opened to recruitment	Total randomised
1	John Radcliffe Hospital	27.09.2022	6
2	University Hospital Coventry	05.12.2022	5
3	Milton Keynes University Hospital	24.10.2022	4
4	Croydon University Hospital	19.12.2022	4
5	King's Mill Hospital	28.09.2022	4
6	Poole Hospital	05.12.2022	3
7	Tameside Hospital	24.10.2022	3
8	Blackpool Victoria Hospital	07.11.2022	3
9	Chesterfield Royal Hospital	17.11.2022	2
10	Whittington Hospital	06.12.2022	1
11	Russell's Hall Hospital	05.12.2022	1
12	Kettering General Hospital	05.10.2022	1
13	Royal Liverpool Hospital	13.12.2022	1
14	Chelsea and Westminster Hospital	25.01.2023	1
15	Churchill Hospital	20.10.2022	0
16	Royal Cornwall Hospital	17.10.2022	0
17	Basingstoke Hospital	14.11.2022	0
18	Royal Hampshire County Hospital	14.11.2022	0
19	Great Western Hospital	19.12.2022	0
20	Pilgrim Hospital, Boston	12.01.2023	0
21	Leicester Royal Infirmary	16.01.2023	0
22	Royal Berkshire Hospital	23.01.2023	0
23	West Middlesex University Hospital	06.02.2023	0
24	Queen Elizabeth Hospital, Woolwich	08.02.2023	0
25	Hull Royal Infirmary	13.02.2023	0
26	Northumbria Emergency Specialist Hospital	17.02.2023	0
27	Frimley Park Hospital	20.02.2023	0

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## Screening Logs

- Patients are entered onto the screening log either:
  - Once a patient has platelets less than 50 and continues to be screened daily until screening is completed (patient recruited, excluded or discharged), OR
  - Once screening is completed (patient recruited, excluded or discharged)
- Screening tools are provided for optional use

# Screening Tool

- This is an optional tool which may be useful for daily patient review (1 page per patient)

T4P Screening Tool V2.0 11 Jan 2023



## T4P Screening Tool

One per patient

(Optional - does not need to be submitted to ICNARC CTU.)

Patient initials:  
Hospital number:

Date of screen	Time of screen	INCLUSION CRITERIA (all must be Yes)				EXCLUSION CRITERIA (all must be No) & see guide below								If all inclusion criteria YES and all exclusion criteria NO then patient is eligible and can be randomised into the trial.	Eligibility confirmed by Initials of staff	If randomised: Trial Number	If not randomised: reason
		1. Age ≥18 years	2. Accepted for or admitted to crit care unit	3. Platelet count <math><50 \times 10^9/L</math>	4. Planned to undergo a specified low bleeding risk invasive procedure OR platelet transfusion being considered for an 'other' procedure	1. Ongoing major haemorrhage	2. Intracranial haemorrhage within 72hr	3. Contra-indication to platelet transfusion	4. Acute promyelocytic leukaemia (APML)	5. Known advanced decision refusing blood products	6. Death imminent or palliation	7. Previously randomised to T4P	8. Fulfilled all inclusion criteria $\geq 72$ hrs				

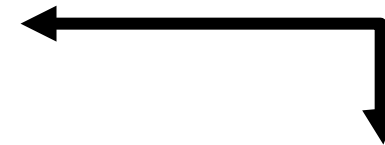
Unsure if a patient is eligible? Contact:  
Your Principal Investigator or research team for assistance  
• ICNARC CTU: 020 7269 9284 or [T4P@icnarc.org](mailto:T4P@icnarc.org)

Please enter each patient on the T4P screening log when screening complete



# Screening Logs

- Each patient is a separate row on the screening log
- Please also complete column E about whether the patient is having a planned procedure or not



Always complete the date of admission

	A	B	C	D	E	
	Date of critical care unit admission (dd/mm/yy)	Aged ≥18 years?	Accepted for admission or admitted to critical care unit	Platelet count <math>50 \times 10^9/L</math>	Planned to undergo a specified* low bleeding risk invasive procedure OR platelet transfusion being considered for an 'other' procedure	Proce (for all p where no pl
1						
2	15/02/2023	Yes	Yes	Yes		
3					Yes - planned to undergo a specified low bleeding risk procedure	
4					Yes - platelet transfusion being considered for 'other' procedure	
5					No - platelet transfusion not being considered for 'other' procedure	
6					No - procedure deemed high risk	
7					No - no procedure planned	
8					No - other, explain in comments	

## Screening Logs

- Record all patients on critical care with platelet count  $<50 \times 10^9/L$
- Please note that platelet count must be below  $50 \times 10^9/L$  to go onto the log so this inclusion should always be marked as 'yes'
- This inclusion criteria should not change as you screen patients -
  - e.g., even if their platelet count goes above/below 50 during their stay, the 'Platelet count  $<50 \times 10^9/L$ ' inclusion remains 'yes' as this was the case at time of start of screening
- Please complete the procedure name for all scenarios where the patient is having any planned procedure, even if a platelet transfusion is not being considered or the procedure is deemed high-risk



# Screening Logs

- The screening outcome can be listed as ‘screening ongoing’ during the screening process, but this should be updated to one of the other options as soon as the patient has completed screening
- Please also note that if no procedure is planned then the screening outcome is ‘not randomised - did not meet all inclusion’ regardless of any exclusions also met

N	O	P						
Met all the inclusion criteria Met none of the exclusion criteria ≥ 72 hours Add reason (Section E)	Screening Outcome	Trial ID Number						
<table border="1"> <tr> <td>Randomised (complete Trial Number)</td> </tr> <tr> <td><b>Not randomised - Screening ongoing</b></td> </tr> <tr> <td>Not randomised - Did not meet all inclusion criteria</td> </tr> <tr> <td>Not randomised - Met ≥ 1 exclusion criteria</td> </tr> <tr> <td>Eligible not randomised (complete Section E)</td> </tr> <tr> <td>Not randomised - Eligibility unknown</td> </tr> </table>			Randomised (complete Trial Number)	<b>Not randomised - Screening ongoing</b>	Not randomised - Did not meet all inclusion criteria	Not randomised - Met ≥ 1 exclusion criteria	Eligible not randomised (complete Section E)	Not randomised - Eligibility unknown
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## Screening Log Scenarios

Inclusion criterion #4 (low bleeding risk procedure)

- Higher than anticipated rates of ‘*no procedure planned*’ reported for patients not meeting this inclusion
  - Possible scenarios?
    - Patient doesn’t have low bleeding risk procedure (the obvious)
    - Or
    - Low bleeding risk procedures being carried out before critical care admission, e.g., in the emergency department or ward?

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# Screening Log Update

- Updates will be made to the screening log
  - V2.1 will be sent round in the next week or so
  - Additional detail regarding date of final screen and questions about pre-critical care procedures
- SOP 003: Patient Screening
  - Explanations provided on completion of the screening log
  - Located in section 3 of the ISF
  - Update will be circulated
  - [T4P@icnarc.org](mailto:T4P@icnarc.org) for queries



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## Standard Operating Procedure (SOP)

### Patient screening

SOP 003

Scope

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To provide guidance on screening patients for inclusion into the T4P trial and on completion of the Screening Log and Enrolment Log.

Screening

- Potentially eligible patients admitted/accepted for admission to the participating critical care unit will be screened against the inclusion/exclusion criteria by the local clinical team, supported by the research team.
- Only staff members that have received trial training (i.e., in how to screen patients), as recorded on the Training Log (section 12 of the Investigator Site File (ISF)), are able to screen patients for eligibility. However, these staff do not require GCP training if their only task on the trial is to screen and randomise.

## Questions/site discussion

- Any questions?



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