



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 - 11 January 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
- Substantial amendment #1
- Questions/site discussion

Trial Update

- Open sites: **18**
- Recruitment to date: **25**
- Recruitment in January so far: **5**

	Site name	Date opened to recruitment	Total randomised
1	John Radcliffe Hospital	27.09.2022	5
2	Milton Keynes Hospital	24.10.2022	4
3	King’s Mill Hospital (Sherwood)	28.09.2022	3
4	Poole Hospital	05.12.2022	3
5	University Hospital Coventry	05.12.2022	2
6	Tameside	24.10.2022	2
7	Russell’s Hall Hospital	05.12.2022	1
8	Chesterfield Royal Hospital	17.11.2022	1
9	Croydon University Hospital	19.12.2022	1
10	Kettering General Hospital	05.10.2022	1
11	Blackpool Victoria Hospital	07.11.2022	1
12	Royal Liverpool Hospital	13.12.2022	1
13	Basingstoke Hospital	14.11.2022	0
14	Churchill Hospital	20.10.2022	0
15	Royal Cornwall Hospital	17.10.2022	0
16	Royal Hampshire County	14.11.2022	0
17	Whittington Hospital	06.12.2022	0
18	Great Western Hospital	19.12.2022	0
			25

Agenda

- Trial update
- **Substantial amendment #1**
- Questions/site discussion

Substantial Amendment #1

Inclusion criterion no.4

- Previous wording:
 - Platelet transfusion being considered for a low bleeding risk invasive procedure
- New wording:
 - Planned to undergo a specified* low bleeding risk invasive procedure OR platelet transfusion being considered for an ‘other’ procedure

Substantial Amendment #1

Inclusion criterion no. 4 (cont.)

- *Specified low bleeding risk invasive procedures include the following:
 - Central venous vascular catheter insertion (including vascular access for renal replacement therapy)
 - Paracentesis/superficial abdominal fluid collection drainage
 - Pleural aspiration

Substantial Amendment #1

Inclusion criterion no. 4 (cont.)

- ‘Other’ procedures may be included if the clinician deems these to be a low bleeding risk invasive procedure and a platelet transfusion is being considered for the procedure. These include, but are not limited to, the following:
 - Arterial catheter insertion
 - **Arterial or central venous catheter removal**
 - Pleural drain
 - Interventional radiology
 - Bronchoscopy with or without lavage
 - Wound dressing changes
 - Surgical procedures where the clinical team agree risk of bleeding is low, e.g., re-look laparotomy, or wound closure

Substantial Amendment #1

Exclusion criteria updates

- Addition of **acute promyelocytic leukaemia (APML)**
- Minor wording change '**Known** advance decision refusing blood/blood component transfusions (e.g., Jehovah's Witnesses)

Safety reporting process updates

- Updates to the way you report a SAE have been reflected in the protocol
 - No longer need to submit a paper SAE Report Form
 - Report SAE directly onto MACRO - PI sign off is electronic
- This process has already been implemented on MACRO

Substantial Amendment #1

What happens next?

- Implementation date: 12 January 2023 (tomorrow!)
- Sealed Envelope will deploy changes to eligibility criteria
 - Once deployed, we will send the implementation email to sites
- Documents to be implemented:
 - Protocol V2.0
 - Randomisation Form V2.0
 - Screening Log V2.0
 - Screening Tool V2.0 (optional)
 - SOP003 Patient Screening V2.0
 - ISF Checklist V2.0

P.S. New laminated staff posters will be posted out

Questions/site discussion

- Any questions?



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