



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 May 2024

IRAS ID: 312405 / 328271

NIHR CPMS ID: 53274

REC Ref: 22-SC-0186 / 23-SS-0082

ISRCTN Registry: ISRCTN79371664

Funding: NIHR HTA (131822)

Sponsor: University of Oxford

Chief Investigator: Prof Peter Watkinson

Agenda

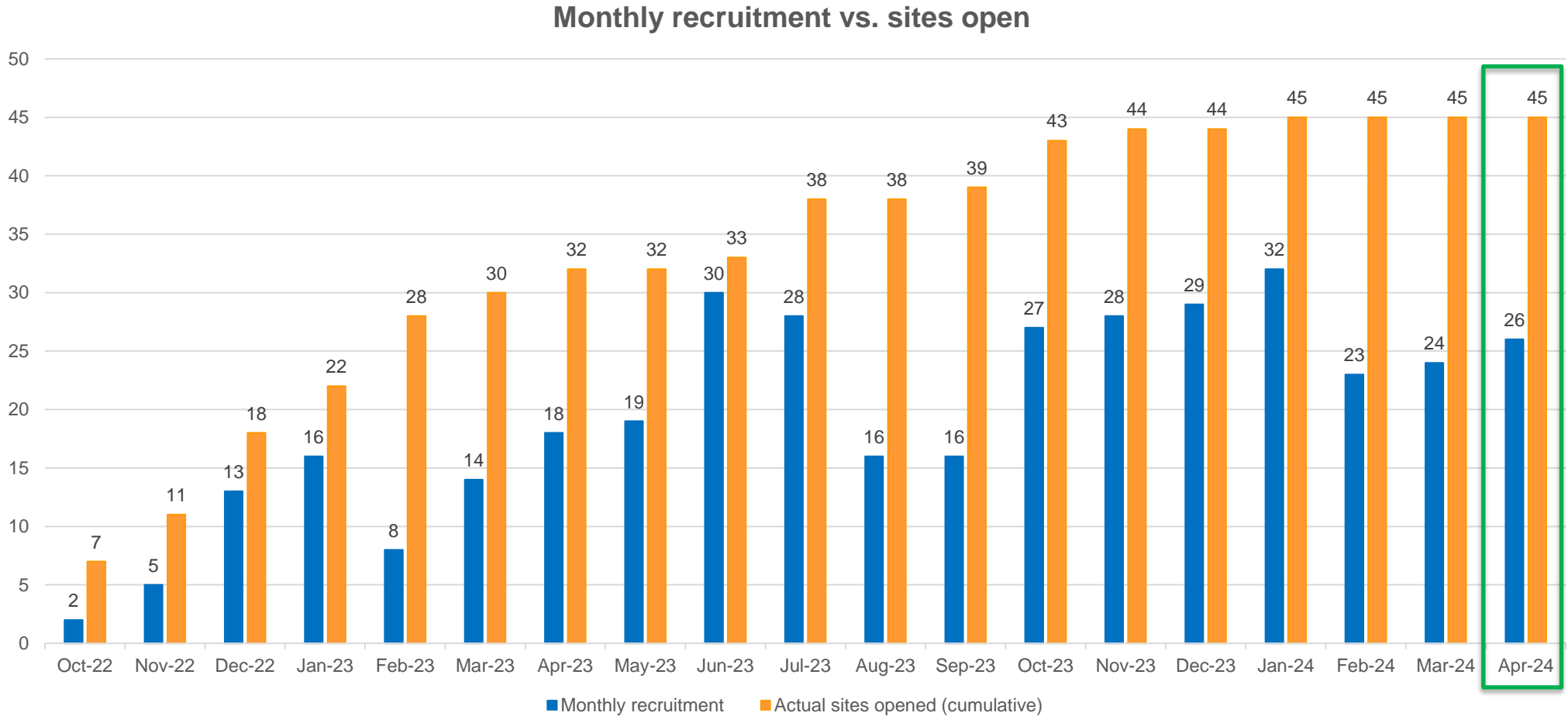
- Trial update
 - Sites
 - Recruitment
- MACRO Screening Logs
- Questions/site discussion

Trial Update - Sites

- Aim: **66**
- Open: **46**
 - Since our last meeting, welcome to:
 - **Western General Hospital, Edinburgh**
- In set up: **11**
- Still accepting expressions of interest
 - If you have other hospitals within your Trust who could take part, do speak to them/us

Trial Update - Recruitment

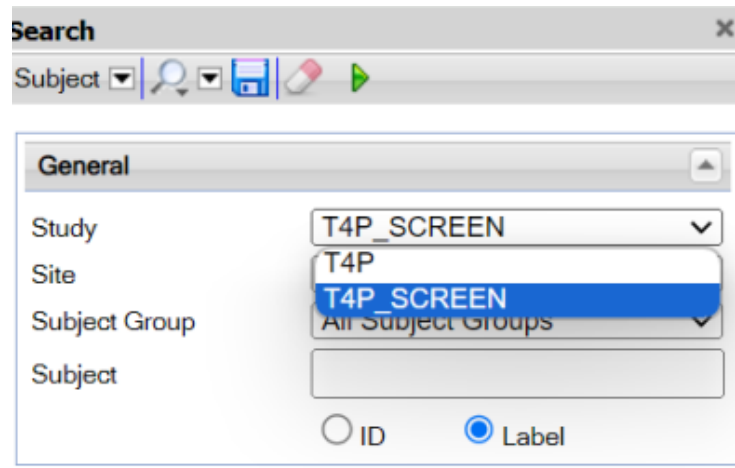
- As of 20 May 2024, **392** patients randomised



Recruitment displayed to 30 April 2024

MACRO Screening Logs

- All patients with platelet count <50 accepted/admitted to critical care go onto the screening log
- Validations are set up so only sections applicable will open
- Missing data will appear as an orange sun and will come through in your missing pages reports



- Adding New Patients
 - Screening number is automatically generated and corresponds to the page/row on MACRO
 - E.g., 1_1 = Page 1, Row 1
 - Use new version of the Enrolment Log excel file as a key to match patient with screening number
 - Record ICU admission and date screening started

	Screening number	Date of critical care unit admission	Date screening started
✓ 1.	1_1	30/10/2023	✓ 31/10/2023 ✓

- Inclusion Criteria
 - Confirm whether met the age inclusion
 - Confirm whether met the procedure inclusion
 - We want to know whether they met the procedure inclusion when their platelet count was <50 (not when it was >50)

INC: Aged >=18 years?	INC: Planned to undergo a specified low bleeding risk invasive procedure OR platelet transfusion being considered for an 'other' procedure	INC: Procedure name
<input checked="" type="radio"/> Yes <input type="radio"/> No	✓ No - only 'other' procedure/s received and platelet transfusion never considered	✓ Central and Arterial line removal
<input checked="" type="radio"/> Yes <input type="radio"/> No	✓ No - no procedure received during screening	
<input checked="" type="radio"/> Yes <input type="radio"/> No	✓ No - no procedure received during screening	
<input checked="" type="radio"/> Yes <input type="radio"/> No	✓ No - no procedure received during screening	
<input checked="" type="radio"/> Yes <input type="radio"/> No	✓ Yes - planned to undergo a specified low bleeding risk procedure	✓ Central and Arterial line insertion
<input checked="" type="radio"/> Yes	✓ Yes - platelet transfusion considered for 'other' procedure	✓ Arterial line insertion

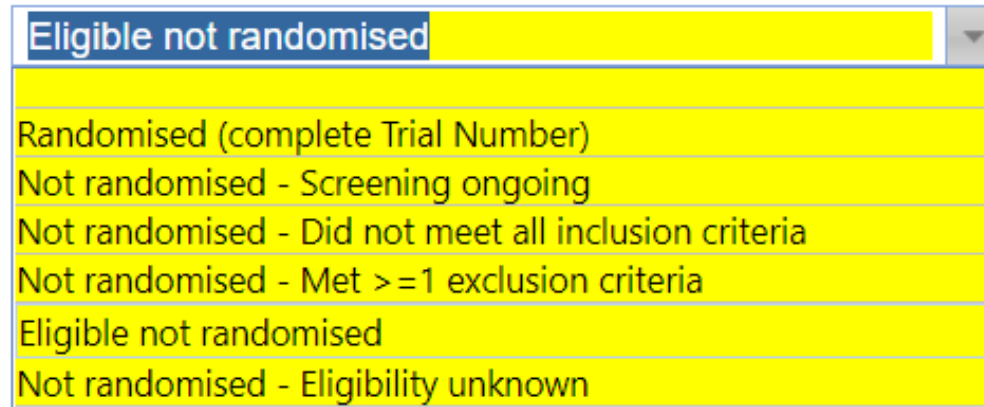
• Exclusion Criteria

EXC: Ongoing major haemorrhage requiring blood products and/or surgical/radiological intervention	EXC: Intracranial haemorrhage within prior 72 hours	EXC: Contraindication to platelet transfusion	EXC: Acute promyelocytic leukaemia (APML)	EXC: Advance decision refusing blood/blood component transfusions	EXC: Death perceived as imminent or admission for palliation	EXC: Previously randomised into T4P	EXC: Fulfilled all the inclusion criteria and none of the other exclusion criteria => 72 hours
<input type="radio"/> Yes <input checked="" type="radio"/> No	<input type="radio"/> Yes <input checked="" type="radio"/> No	<input type="radio"/> Yes <input checked="" type="radio"/> No	<input type="radio"/> Yes <input checked="" type="radio"/> No	<input type="radio"/> Yes <input checked="" type="radio"/> No	<input type="radio"/> Yes <input checked="" type="radio"/> No	<input type="radio"/> Yes <input checked="" type="radio"/> No	<input type="radio"/> Yes <input checked="" type="radio"/> No

• Procedure pre-ITU

If yes, what was the platelet count prior to this procedure being done? (x10 ⁹ L)	If yes, at what location was the procedure done?	If yes, provide procedure name	Screening Outcome
<input type="text" value="33"/> <input checked="" type="checkbox"/>	<input type="text" value="Ward"/> <input checked="" type="checkbox"/>	<input type="text" value="Arterial Line"/> <input checked="" type="checkbox"/>	<input type="text" value="Randomised (complete Trial Number)"/>

- Screening Outcome
 - Add the screening outcome
 - No procedure during screening/only ‘other’ or high-risk procedures = not randomised - did not meet all inclusion criteria
 - Please ensure any ‘screening ongoing’ is updated as soon as you can



A screenshot of a dropdown menu with a yellow background. The menu is open, showing the selected option 'Eligible not randomised' at the top. Below it are several other options: 'Randomised (complete Trial Number)', 'Not randomised - Screening ongoing', 'Not randomised - Did not meet all inclusion criteria', 'Not randomised - Met >=1 exclusion criteria', 'Eligible not randomised', and 'Not randomised - Eligibility unknown'.

Eligible not randomised
Randomised (complete Trial Number)
Not randomised - Screening ongoing
Not randomised - Did not meet all inclusion criteria
Not randomised - Met >=1 exclusion criteria
Eligible not randomised
Not randomised - Eligibility unknown

Eligible not randomised

- Select one of the reasons eligible not randomised:
 - Missed/Identified too late
 - Clinical decision
 - Non-clinical decision - e.g., patient refused CVC insertion
 - Co-enrolment issue
 - Prospectively refused consent - includes patient and NOK refusals
 - Other reason - should be used very rarely
- Please provide context for each reason in the ‘reason why eligible not randomised’ box (this will flag as missing if not completed)
- Document: Study Manual

Questions?

- What are your thoughts on the new process?
- Have any screening scenarios happened you are not sure how to record?

Coming up...

- Next **Associate PI** session:
 - 04 June 2024 12:00 - 13:00
 - Please encourage your Associate PIs to join and share tips, as well as ask the CI any questions
- Next **drop-in** session:
 - w/c 10 June 2024
 - Reminder, this session is for:
 - Staff who require training to perform eligibility/randomisation tasks
 - Staff who would like a refresher/recap/chance to ask questions
 - Anyone who needs training to go onto the delegation log requires full (SIV) training
- Next **T4P Investigators Meeting!**
 - 13 September 2024 in London
 - Registration email will be sent out this week

Questions/site discussion

- Any questions?

Thank you!



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