



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 - 28 February 2024**

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
  - Sites
  - Recruitment
- Screening Logs
- Questions/site discussion

# Trial Update - Sites

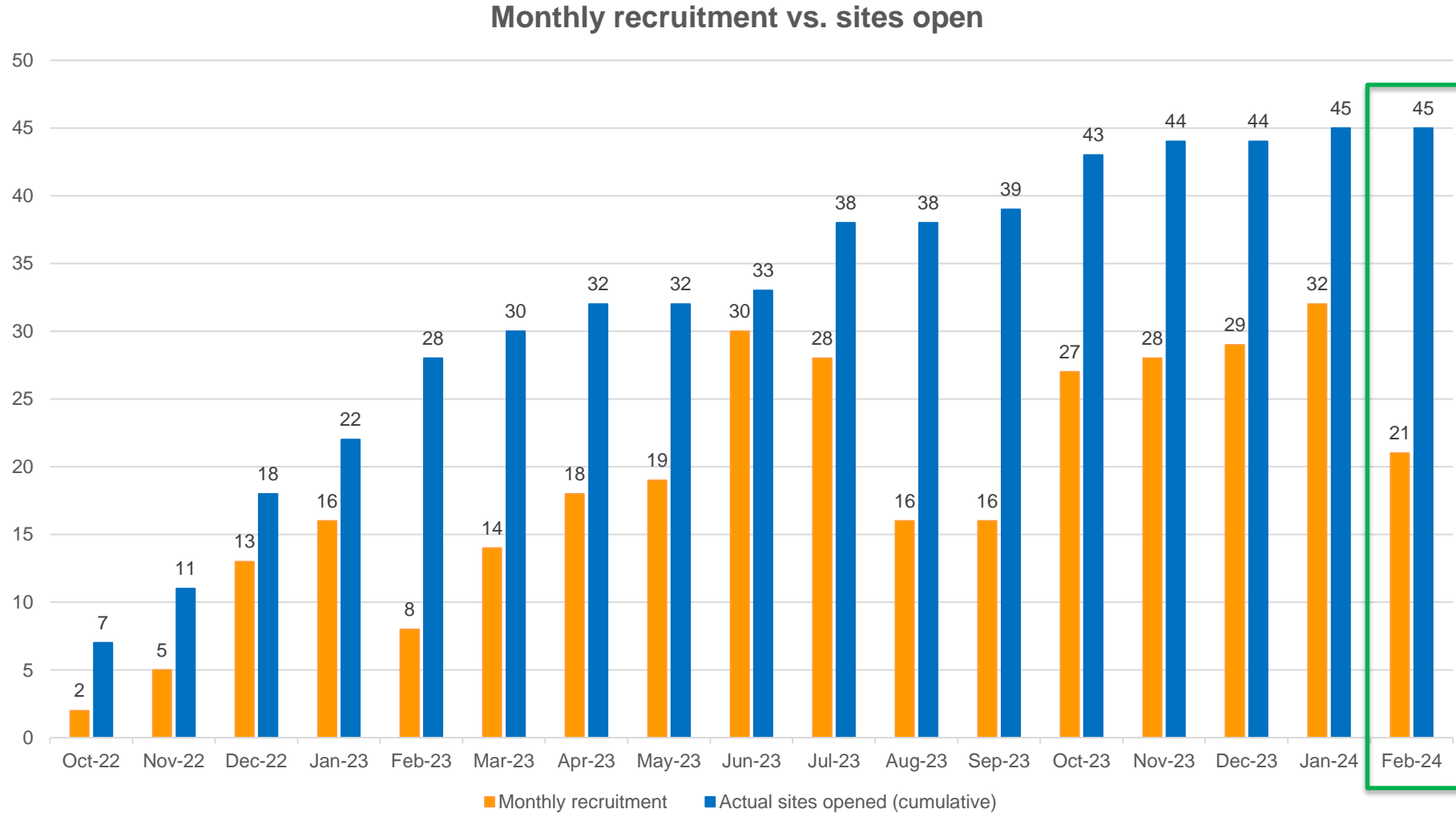
- Aim: **66**
- Open: **45**
  - Since our last meeting, welcome to:
    - **University Hospital Lewisham**
- In set up: **8**
- Still accepting expressions of interest
  - If you have other hospitals within your Trust who could take part, do speak to them/us

## Trial Update - Recruitment

- As of 27 February 2023, **322** patients randomised
  - **300<sup>th</sup>** patient = University Hospital of North Durham!


# Trial Update - Recruitment

- Monthly recruitment up to 27 February 2024



# Screening Logs

- Screening log completion is moving to MACRO
- Current process:
  - Screening data entered onto Excel spreadsheet
  - Spreadsheets submitted monthly to CTU - with identifiers removed
  - Queries generated via email

Remove local identifiers prior to submission to ICNARC				T4P Screening Log - Record all patients <u>accepted or admitted</u> c			
				Each row represents a patient admission. Patients should be added once per Critic			
				<i>(Use optional local site screening tool to aid screening of each patient during their whole admission)</i>			
Section A: Patient details				Section B: Inclusion			
				1	2	3	
Local identifier <i>(remove prior to submission to ICNARC)</i>	CMP number (202xxxx) <i>(remove prior to submission to ICNARC)</i>	Date of critical care unit admission (dd/mm/yy)	Date screening started <i>(i.e. date platelets first recorded below 50)</i>	Aged ≥18 years?	Accepted for admission or admitted to critical care unit	Is platelet count <50x10 <sup>9</sup> /L?	Planned to undergo a specified OR platelet transfusion being

## Screening Logs

- New process:
  - Screening data entered onto MACRO
  - Sites can enter on a continual basis
  - No collection of identifiers = no risk of sending identifiers via email
  - Validations in place to help with data entry (i.e., cannot enter illogical scenarios)
  - Queries via DCRs on MACRO

# Screening Logs

- Excel screening logs up to 31 Jan 2024 will be uploaded into the new MACRO format
  - Sites will need to enter any additional patients from 01 Feb 2024 onwards
- Navigating to your MACRO screening log:

In your patient list:

...
T4P
T4P
T4P
T4P
T4P
T4P
T4P
T4P_SCREEN

When you select T4P\_SCREEN:

T4P_SCREEN/ncaa5mt/(1)	T4P
Screening Log	✓
Screening Log [2]	✓
Screening Log [3]	✓
Screening Log [4]	☀
Screening Log [5]	✓

Each 'Log' has 10 rows



# Screening Logs

## Screening Log



Please add all patients with a platelet count of <math><50 \times 10^9/L</math> who are accepted/admitted to your critical care unit to the screening log.

Screening number	Date of critical care unit admission	Date screening started	INC: Aged $\geq 18$ years?	INC: Planned to undergo a specified low bleeding risk invasive procedure OR platelet transfusion being considered for an 'other' procedure
1. 1_1	16/12/2022	18/12/2022	<input checked="" type="radio"/> Yes <input type="radio"/> No	No - no procedure received during screening
2. 1_2	19/12/2022	23/12/2022	<input checked="" type="radio"/> Yes <input type="radio"/> No	Yes - planned to undergo a specified low bleeding risk procedure
3. 1_3	21/01/2023	24/01/2023	<input checked="" type="radio"/> Yes <input type="radio"/> No	Yes - platelet transfusion considered for 'other' procedure
4. 1_4	23/01/2023	27/01/2023	<input checked="" type="radio"/> Yes <input type="radio"/> No	Yes - planned to undergo a specified low bleeding risk procedure


MACRO assigns a 'screening number'

MACRO screening log mimics excel log:

- Same data captured, apart from identifiers

# Screening Logs - updated documentation

- Enrolment Log V2.0
  - New: Screened Patients tab
  - To help you keep a key of screened patients (should you need to check back for any queries locally)
  - Enrolment Log does not need to be sent to ICNARC CTU
- CRF Guidance V4.0
- Study Manual V1.1
- ISF Checklist V4.0

 <b>Screened Patients (Key)</b>			
All screened patients should be added to the Screening Log on MACRO. This tab is recommended to keep a record to enable identification of screened patients should any data queries arise. This log is for local use only - <b>do not send</b> to ICNARC CTU			
Screening number <i>(generated on MACRO, e.g., 3_1)</i>	Patient name	Hospital/NHS number	CMP number

## Screening Logs

- We will be contacting sites individually from tomorrow onwards to switch your logs over to MACRO
- Hopefully the new process is a lot easier for you!

## Coming up...

- Next **drop-in training** session:
  - W/C 25 March 2024
- **T4P Clinical Webinar:**
  - Thursday 07 March 2024 11:30-12:30
  - Update on trial progress, adherence, clinical Q&A
  - Do forward flyer on to wider teams

## Questions/site discussion

- Any questions?

Thank you!



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