



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 - 30 November 2022

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

Chief Investigator: Prof Peter Watkinson

Agenda

- Trial update
- Eligibility queries
- Screening logs
- Training & site resources
- All site meetings
- Questions/site discussion

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Trial Update

- Open sites: 11
- Current recruitment total: 7
- Sites opened since 27 September 2022
 - John Radcliffe Hospital, Oxford
 - Churchill Hospital, Oxford
 - King's Mill Hospital
 - Kettering General Hospital
 - Milton Keynes University Hospital
 - Tameside General Hospital
 - Blackpool Victoria Hospital
 - Royal Hampshire County Hospital
 - Basingstoke and North Hampshire Hospital
 - Chesterfield Royal Hospital



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Eligibility Queries

Inclusion criteria no. 4

- Platelet transfusion being considered for a *low bleeding risk invasive procedure* - what does this mean?
 - The patient is planned for an invasive procedure imminently, that is considered low bleeding risk and a platelet transfusion is being considered for this procedure
 - You are randomising the patient for this procedure, and they must be randomised prior to the procedure

Which platelet count should I use for randomisation?

- The most recent prior to randomisation, taken as part of routine care
- You do not need to take an additional blood sample for platelet measurement purely for the purpose of the trial - but do check for the latest value before you randomise
- This platelet count is recorded on Sealed Envelope at point of randomisation

What if the first procedure doesn't go ahead?

- A patient is only eligible if a procedure is planned imminently
- Check eligibility and randomise as close to the planned procedure as possible (recognising that adequate time needs to be allowed to order platelets if randomised to a threshold level that means they will need a platelet transfusion)
- If the planned procedure does not go ahead, the patient remains in the trial. For any future procedure their allocated threshold remains & platelets given accordingly
 - Complete the eCRF as usual, for daily data day 1 “*Received low bleeding risk invasive procedure today*” Select “NO”. This will flag as a query - enter the reason

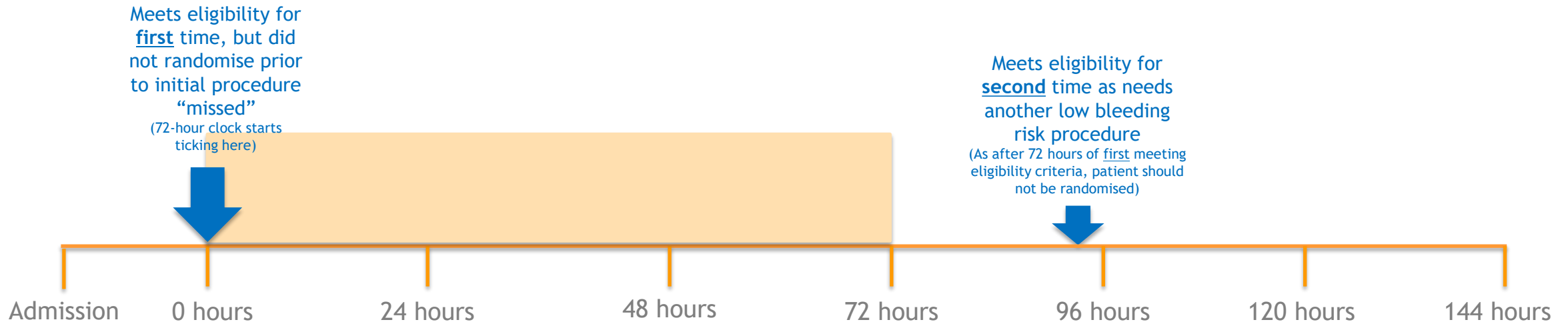
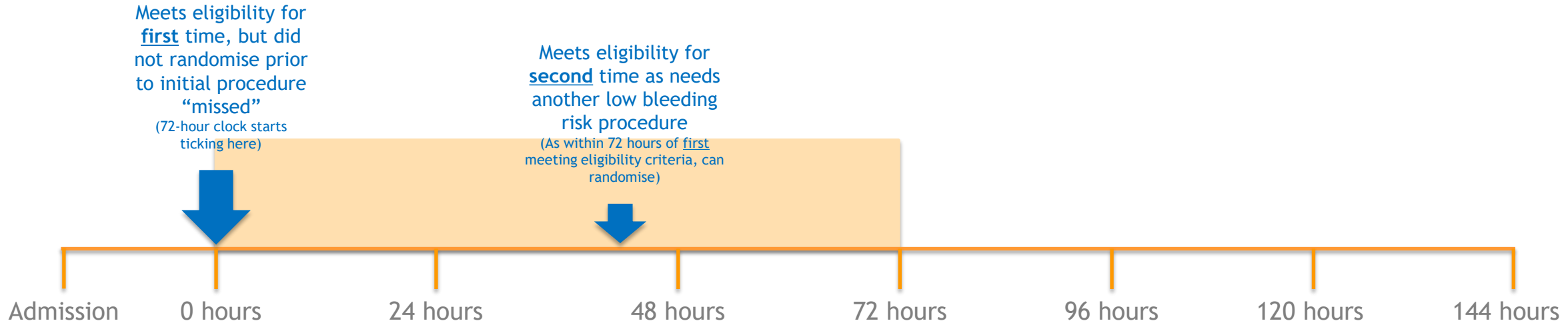
Eligibility Queries

Exclusion criteria no. 7

Fulfilled all the inclusion criteria and none of the other exclusion criteria ≥ 72 hours - what does this mean?

- When does the 72-hour clock start ticking?
 - Once the patient meets all of the inclusion criteria
 - Adult AND platelets <50 AND accepted or admitted to critical care unit AND platelets considered for a low bleeding risk procedure
 - AND the patient meets none of the exclusion criteria
 - Haemorrhage, contra-indication to platelets, advance decision, death imminent/palliation, previously randomised to T4P
- The clock does not start ticking just because the patient has platelets <50 , this is only one part of the eligibility assessment
- If the patient initially meets all inclusion, but meets exclusion criteria no. 1 or 2 (major haemorrhage and intercranial haemorrhage) - the clock does not start ticking as they are not eligible at this point
 - If these exclusions resolve however, and the patient later needs a low bleeding risk procedure (and they meet all other inclusion like platelets still being <50) then they become eligible for the first time, and the clock starts ticking

Exclusion criteria no 7 - Scenario



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Screening Logs

- All logs get imported to a central master spreadsheet by ICNARC so please don't change any formatting on the template
- **Reminder:** please remove columns A (patient identifiers) and column B (CMP number) before sending to ICNARC
 - If data in columns A and B are not removed then this is a data breach
- Record all patients with platelet count $<50 \times 10^9 / L$
- Mark 'X' if exclusion met, or leave blank if not met

Screening Logs

- We will continue to ask for screening log every 2 weeks
- Please use the newest version - 'V1.1 17.11.2022'
- Please complete 'Screening Outcome' using drop down options



		Section C: Exclusion criteria (mark 'x' in relevant column if exclusion criteria met)							Section D: Screening Outcome		Section E
4		1	2	3	4	5	6	7			
Procedure name <i>(for all patients, except where no procedure is planned)</i>	Ongoing major haemorrhage requiring blood products and/or surgical/radiological intervention	Intracranial haemorrhage within prior 72 hours	Contraindication to platelet transfusion <i>(specify contraindication below)</i>	Advance decision refusing blood/blood component transfusions	Death perceived as imminent or admission for palliation	Previously randomised into T4P	Fulfilled all the inclusion criteria and none of the other exclusion criteria ≥ 72 hours <i>(please add reason in Section E)</i>	Screening Outcome	Trial ID Number	If eligible but not randomised OR met exclusion no. 7, select reason below and explain in comments	
								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 (complete Section E)			
								Not randomised - Eligibility unknown			

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Training & Resources

- SIV slides & recording
- Screening and randomising training slides
- Eligibility recap (exclusion no.7 explained)
- ‘Grab pack’ site working files
- Sealed Envelope randomisation quick guide
- Template certificates
- Laminated eligibility posters with QR codes
- Stickers with QR code to screening and randomisation webpage
- Coloured threshold bedside notices
- Pens and post-its coming soon!

Training & Resources

- All resources can be found on our website:
- <https://www.icnarc.org/Our-Research/Studies/Current-Studies/T4P/Information-For-Sites>

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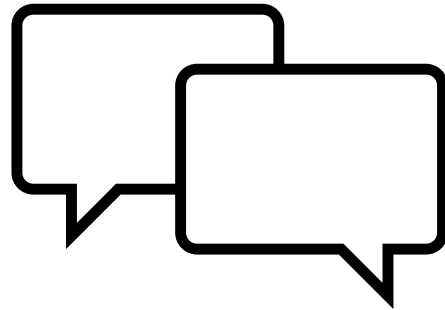
All Site Meeting

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All site meetings

- Going forward we will be looking to hold all-site meetings on a monthly basis:
 - Trial update
 - Bring along any queries
 - Let us know if there is anything you want us to cover



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Questions/site discussion

- Any questions?



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