



T4P All-Site Meeting

30 November 2022

Summary

Eligibility

Inclusion criterion no.4 – “Platelets being considered for a low bleeding risk invasive procedure”

- A patient is only eligible if a (low bleeding risk) procedure is planned imminently. Check eligibility and randomise as close to planned procedure as possible
- The most recent platelet count should be used prior to randomisation. This is recorded on Sealed Envelope at point of randomisation and this platelet count should be used to guide intervention for the initial low bleeding risk invasive procedure, even if further central lab results have become available after randomisation

Exclusion criterion no.7 – “Fulfilled all the inclusion and none of the other exclusion criteria \geq 72 hours”

- The 72-hour clock starts ticking once patient meets all inclusion criteria AND none of the exclusion criteria
- If the patient is not randomised when they first become eligible (they are ‘missed’), the patient could still be randomised within 72 hours of this point, providing they become eligible again (i.e., require another low bleeding risk procedure)
- The 72-hour clock does not start ticking just because the patient has platelets $<50 \times 10^9/L$, this is only one inclusion criteria
- They can become eligible for the first time at any point on their critical care stay

Screening

- Reminder to use the template provided and not change formatting so all logs can be pulled into a central spreadsheet at ICNARC – use latest version V1.1 17.11.2022 log
- Remember to please remove column A (local patient identifiers) and column B (CMP number) before sending to ICNARC or this will have to be reported as a data breach
- Use 1 of 6 drop down options to record the screening outcome before sending the log to us and to please keep this consistent

Training & Resources

- There are lots of resources available for sites including, SIV training slides and recordings, ‘grab packs’, randomisation quick guides, certificates, laminated posters with QR codes, and coloured threshold bedside notices etc.
- FAQs will also be updated on our website regularly
- <https://www.icnarc.org/Our-Research/Studies/Current-Studies/T4P/Information-For-Sites>

Question/discussion:

- Some concerns with equipoise amongst consultants for the less than 10 arm at one site – important to look at the education webinar on our website with the background of the study and remember

there is little evidence base currently – suggestion that the PI is more involved in the first couple of potential randomisations at site while the trial gets underway

- Can liver failure patients be included in T4P? – yes, they are not an exclusion so should be included in the trial if deemed appropriate by clinical staff

Thank you for your continued hard work on the trial!