



T4P All-Site Meeting

11 January 2023

Summary

Substantial Amendment #1

Inclusion criterion no.4

- New wording – “planned to undergo a specified* low bleeding risk invasive procedure OR platelet transfusion being considered for an ‘other’ procedure”
- Specified procedures including:
 - Central venous vascular catheter insertion (including vascular access for renal replacement therapy)
 - Paracentesis/superficial abdominal fluid collection drainage
 - Pleural aspiration
- Central venous catheter *removal* moved to ‘other’ procedures list

Exclusion criteria updates

- Addition of acute promyelocytic leukaemia (APML)
- Minor wording change – “Known advance decision refusing blood/blood component transfusions”

Safety Reporting Process

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- No longer need to submit a paper SAE Report Form
- SAE can be reported directly on MACRO, with electronic PI (or delegate) sign off

Implementation

- The substantial amendment will be implemented **Thursday 12th January**
- We will send an implementation email out including the new versions of trial documents – this will include updated staff posters and we will email these as well as post out new laminated copies soon
- Please get in touch with us if you have any queries about the new amendment and its implementation at your site

Recruitment Tips and Tricks:

Lots of great ideas from sites on how to improve recruitment:

- Screen the critical care unit every morning (preferably after bloods have been done)
- Posters around the unit plus drop-in sessions showing trial slides... and cake!
- Paper handover sheets at ward rounds to remind staff of research
- Team WhatsApp group to help communicate about potential patients

Thank you for your continued hard work on the trial!