ICNARC
Napier House
24 High Holborn
London WC1V 6AZ
tel +44(0)20 7269 9277
email T4P@icnarc.org

T4P All-Site Meeting

03 July 2023
Summary

Drop-in Training Sessions

- We will try to run monthly drop-in training sessions to assist sites with high staff turnover and new trainees coming in every 6 months
- Staff don't need GCP as they will only be screening/randomising – but do need to be signed off on the training log following the session
- A link to the first drop-in session will be emailed to sites in August and can be passed onto any team members who may be interested
- Certificates are available on our website here although we may give these out for you to those who attend the training sessions

Bedside Training

- A suggestion from the Investigator Meeting was to have an A4 sheet quick guide for staff to be given an overview of T4P at the bedside to increased study awareness
- We have now created a template for this which is attached to this email

72-hour Window

- Still some confusion about the 72-hour window – please see attached a couple of slides to clarify this
- Patients can become eligible at any point during their ITU stay and 72-hour clock only starts once patient meets *all* eligibility criteria, including low platelets and a procedure

Issues With Platelet Availability

- Some sites have been finding it difficult to get platelets in a timely manner
- District General sites also don't have enough platelets on site and sometimes must wait a long time to receive these
- If there is an emergency situation then please follow standard practice and we understand this is a valid reason for deviation – please just record on the CRF for our records
- We are a pragmatic trial and understand it is not always possible to receive platelets in time before a procedure

Transfusions Outside of Procedures

- Platelet transfusions are permitted outside of procedures according to standard practice
- Please record all transfusions given each day in the daily data pages of the CRF

Transfer of Patients to Other Sites

- If the receiving site is in T4P
    - The aim is for the allocated treatment to be continued if possible, but this is not mandated.
    - The eCRF (MACRO) can be transferred to the receiving site as they are participating in T4P. The randomising site must ensure data collection is up to date on the eCRF to enable the transfer.
    - The research team at the randomising site should communicate the consent progress to the receiving site – which can be continued by research staff at the receiving site with the consultee/patient.
- If the receiving site is *not* a T4P site
    - The receiving site should be notified of patient enrolment and trial treatment; however, it would be up to them to consider whether they will continue the allocated treatment. No treatment and adherence data will be collected whilst the patient is at the receiving site and the eCRF (MACRO) will not be transferred.
    - It is still the randomising site's responsibility to continue the consent process. However, daily data while the patient is at the receiving site will not be required.
    - Consent and Outcome data CRFs will need to be completed by the randomising site.
- If you are unsure whether the receiving site is participating in T4P, please email T4P@icnarc.org and the team will let you know and initiate contact with the research team if applicable.
- If the patient is transferred back to the randomising site or transferred to a ward and then readmitted to critical care, within 90 days of randomisation and within the index hospital admission, then please continue treatment according to the allocated threshold.

Thank you for your continued hard work on the trial!