

RINTAG meeting1st November 2022**Clinical Trials Unit Update****1. Status – Public****2. Executive Summary**

This paper provides an update on the clinical trials in organ donation and transplantation that NHSBT Clinical Trials Unit (CTU) are currently managing. There are currently 5 trials which are in set-up or recruitment, which are described in the table below.

Key highlights since previous RINTAG report:

- the SIGNET study continuing to open sites to recruitment. 71 of the planned 76 Trusts/Boards are now open (113 hospitals), with over 350 organ donors randomised so far. Due to some Trust mergers, the team are approaching some Level 3 sites with higher donation potential to open to the study as well.
- the PLUS study remains open at all 7 UK liver transplant centres and is recruiting well. The 6-month internal pilot review is being prepared. The CTU team are working with the Hub Operations team and participating sites to discuss any issues and feedback on the process. The tool developed by DDTS to flag eligible donors is working well.
- the COBALT study is now open at all 6 planned centres. 24 participants have been enrolled.
- the DeFat study is in set-up, the protocol and supporting documents have been approved by the REC. Expected to open in November 2022
- the PLUTO trial and MELODY study have closed to recruitment
- the PITHIA trial (biopsy service) Statistical Analysis Plan and Health Economic Analysis Plan are being drafted.
- the analysis of the ITOPS trial is nearly complete (improving transplant opportunities of patients who are sensitised)

3. Action Requested

The Committee is asked to:

- Note the contents

Table 1. Current OTDT studies managed by the CTU (in set-up or recruitment)

Trial Name	Trial Summary	Chief Investigator(s)	Sponsor	Progress
DeFat	Delivery of Ex-situ deFattening Agents during normothermic liver perfusion for Transplantation– a randomised clinical trial.	Prof Peter Friend Mr Simon Knight Mr Syed Hussain Abbas	University of Oxford	In set up stage. There are 5 participating sites and the target is 60 livers. Received favourable opinion from the REC. Expected start date November 2022
COBALT	Cardiorespiratory Optimisation By AVF Ligation after Transplantation.	Prof Gavin Pettigrew	Cambridge University Hospitals NHS Foundation Trust & the University of Cambridge	All 6 planned centres opened and actively recruiting. 24 Participants are enrolled, against the target of 40. Recruitment has been strong in Cambridge but more challenging in other centres. Recruitment is due to end on 30 Nov 22, pending discussion with the NIHR to extend to the end of January 2023.
PLUS	Utilisation of normothermic machine preservation in extended criteria livers – a national threshold-crossing study.	Prof Peter Friend Mr Simon Knight	University of Oxford	PLUS opened to recruitment on 11 April 2022. All 7 UK liver transplant centres are participating in the study. To date 536 livers were eligible for the study.
SIGNET	Statins for Improving orGaN outcome in Transplantation.	Prof John Dark Dr Dan Harvey	The Newcastle upon Tyne Hospitals NHS Foundation Trust	SIGNET opened to recruitment on 14 September 2021. To date, 71 Trusts (113 hospitals) have opened to recruitment, and 351 donors have been recruited to date.
TWIST	Multicentre, Open-label Randomised Trial of Superficial Wound Drain on Surgical Site Infection in high Body Mass Index (BMI) Kidney Transplant Recipients.	Mr James Hunter	Oxford University Hospitals NHS Foundation Trust	The CTU are providing administrative support to CI to open participating centres. There are currently 11 centres open to recruitment and 250/360 participants recruited to the trial. Recruitment is expected to continue at a positive rate with the support from participating sites.

Completed since previous RINTAG report:

The PLUTO study (Plasma-Lyte usage and assessment of kidney transplant outcomes in children) closed to recruitment after randomising 144 patients across nine trusts. End of study activities are now underway with results expected early in 2023.

The MELODY study (Mass Evaluation of Lateral flow immunOassays to Detect SARS-COV-2 antibody responses in immunocompromised patients) recruited 29,117 immunocompromised patients, including 12,818 transplant recipients. The analysis of factors influencing COVID-19 antibody positivity is in progress.

Author

CTU Management team
October 2022