

RINTAG meeting

27 September 2023
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 9 trials, which are described in the table below.

Key highlights since previous RINTAG report:

- the protocol for the HOPP trial (Hypothermic Oxygenated Pancreas Perfusion) is in development and is currently aiming to begin recruitment in early 2024. The protocol will be shared for review by RINTAG as part of the next email circulation.
- the DeFat study opened to recruitment on 23/02/2023, 4/5 sites are currently open and 5 livers have been randomised to the study
- the SIGNET study is continuing to open sites to recruitment. 89 of the planned 92 Trusts/Boards are now open (143 hospitals), with over 780 organ donors randomised so far.
- the COBALT study has completed recruitment (n=40). Participants are completing the 6-month visits with Last Participant Last Visit expected early November 2023.
- The initial results from the MELODY study have now been published in The Lancet Rheumatology ([https://doi.org/10.1016/S2665-9913\(23\)00160-1](https://doi.org/10.1016/S2665-9913(23)00160-1)).
- the PLUTO trial closed to recruitment in August 2022. The results were released to the TMG in April, the final report was submitted to the funder in May 2023. The study results are being considered for peer-review publication and will be presented at national and international scientific meetings, including the NHSBT Clinical and R&D Conference

3. Action Requested

The Committee is asked to:

- Note the contents

Table 1. Current OTDT studies managed by the CTU
(in **set-up**, **recruitment**, or **follow-up/analysis**)

Trial Name	Trial Summary	Chief Investigator(s)	Sponsor	Progress
HOPP	Investigate the feasibility and safety of Oxygenated Hypothermic Machine Perfusion of pancreas grafts prior to transplantation in clinical practice.	Prof James Hunter	University of Oxford	Protocol and other key documents currently in first draft and being further developed by investigators. Will be submitted to RINTAG as part of next email circulation.
SIGNET-EME	Examine the mechanisms in the potential down regulation of brain stem death induced proinflammatory responses by Simvastatin	Prof Simi Ali	The Newcastle upon Tyne Hospitals NHS Foundation Trust	A mechanistic sub-study of SIGNET, using QUOD samples. In early set-up stage.
DeFat	Delivery of Ex-situ deFating Agents during normothermic liver perfusion for Transplantation– a randomised clinical trial.	Prof Peter Friend Mr Simon Knight Mr Syed Hussain Abbas	University of Oxford	Open to recruitment since February 2023. There will be 5 participating sites and the target is 60 livers. To date, 4 sites are open to recruitment and 5 livers have been enrolled to the study.
SIGNET	Statins for Improving orGaN outcomE in Transplantation.	Prof John Dark Prof Dan Harvey	The Newcastle upon Tyne Hospitals NHS Foundation Trust	SIGNET opened to recruitment in September 2021. To date, 89 Trusts (143 hospitals) have opened to recruitment, and 781 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	Providing administrative support to this study. There are currently 11 centres open to recruitment and recruitment continues.
COBALT	Cardiorespiratory Optimisation By AVF Ligation after Transplantation.	Prof Gavin Pettigrew	Cambridge University Hospitals NHS Foundation Trust & the University of Cambridge	The 40 th and final participant was recruited in April. Due to the extended recruitment period, a contract extension of 7 months is being requested from the NIHR.
PLUS	Utilisation of normothermic machine preservation in extended criteria livers – a national threshold-crossing study.	Prof Peter Friend Mr Simon Knight	University of Oxford	All 7 UK liver transplant centres are participated in the study. The recruitment target of 1035 livers was reached in April 2023. Follow up is ongoing until April-May 2024
MELODY	Mass evaluation of lateral flow immunoassays for the detection of SARS-CoV-2 antibody responses in immunosuppressed people	Dr Michelle Willicombe	Imperial College London	Results relating to antibody positivity published. Awaiting further data from DARS around therapeutics for outcome analysis.
PITHIA	Pre-Implantation trial of Histopathology In renal Allografts	Prof Gavin Pettigrew	Cambridge University Hospitals NHS Foundation Trust & the University of Cambridge	The SAP has been finalised and the database locked with analysis in progress. Results expected October 2023.

Author
CTU team
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