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Statins for improving organ outcome in transplantation

Submission date 09/07/2021	**Recruitment status** Recruiting	[X] Prospectively registered [X] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [X] Record updated in last year
Registration date 03/08/2021	**Overall study status** Ongoing	
Last Edited 20/09/2024	**Condition category** Surgery	

Plain English summary of protocol

Background and study aims

All organs removed from donors have already suffered a degree of damage. As the brain dies (and all of these donors are brain-stem dead) chemicals are released which cause an "inflammation" of the whole body. Measurements of this "inflammation" link to how well the organs function in the recipient after transplant.

Statins are cholesterol-lowering drugs that have benefits across a range of health problems. In particular, statins damp down inflammation in the body and in individual organs. Statins protect the lungs and kidneys in a range of illnesses.

Recently, transplant doctors in Finland linked all this information in an innovative clinical study. Organ donors who were about to donate their heart were randomly allocated to receive a dose of a statin. After the transplant, the recipients who received a heart from a donor who had statins had less heart damage. The numbers were modest, and no survival advantage could be demonstrated. There was a small benefit for lung and liver recipients, but importantly there was no disadvantage in receiving any organ from a donor who had received the drug.

A significant number of hearts and other organs offered for transplant by the donor family are not used; for the heart, this figure is about 75%. The reason for being so selective is that poor function of the donor heart in the recipient is by far the most common cause of death after a transplant. Any step in the donor which might improve the transplanted heart could have a major benefit to the recipient. The same principle applies to all the other organs transplanted.

The aim of this study is to investigate whether giving deceased organ donors a single dose of the drug simvastatin, a very commonly used and safe drug, is beneficial for transplant recipients.

Who can participate?

Adult brain dead organ donors across the UK per year over 4 years

What does the study involve?

Half the donors will receive the drug (in addition to their standard donor care), compared to the other half of donors who will receive standard care only. The drug is given through a tube running into the stomach, already present in 80% of donors, but required to be placed in the other 20%. The drug will be given as soon as the donor family have consented to both organ donation and involvement of their loved one in research.

Half of all the transplant recipients will receive an organ from a donor given the drug. The

researchers will follow the results of transplant, focussing on the heart recipients, but for all those receiving these organs, comparing what happens in those who received the drug-treated organs, and those who did not. This is done with data already collected in the national transplant database. No extra data or blood samples will be needed from recipients.

What are the possible benefits and risks of participating?
Unfortunately, there will be no benefit to the donors but there may be a benefit to the person receiving their organs if they are transplanted. People receiving an organ that has been treated with simvastatin may have better outcomes, and it is hoped that this will mean more organs can be transplanted successfully, but it is not known whether this will be the case. Simvastatin is a licensed drug and one of the most prescribed drugs in the UK. There are some risks associated with taking statins for a long time, but this will be a single dose so these risks are not considered a problem at all for this study. With any drug there is a risk of an allergic reaction. This is expected to be very rare as there has only been one case of this reported.

Where is the study run from?
NHS Blood and Transplant Clinical Trials Unit (UK)

When is the study starting and how long is it expected to run for?
October 2020 to June 2026

Who is funding the study?
National Institute of Health Research (NIHR) (UK)

Who is the main contact?
Miss Amy Evans
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Study website
https://www.nhsbt.nhs.uk/signet/

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
288722

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
CPMS 49404, IRAS 288722

Study information

Scientific Title
Statins in organ donor management: an evaluation of the benefits of a single dose of simvastatin given to potential organ donors declared dead by neurological criteria on outcomes in organ recipients

Acronym
SIGNET

Study objectives
Does treatment of potential organ donors with simvastatin during protocolised care after diagnosis of death using neurological criteria improve outcomes in patients undergoing transplantation?

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 28/06/2021, London - Queen Square Research Ethics Committee (HRA NRES Centre Bristol, 3rd Floor, Block B, Whitefriars, Lewins Mead, Bristol, BS1 2NT, UK; +44 (0)207 104 8061; queensquare.rec@hra.nhs.uk), REC ref: 21/LO/0412

Study design
Randomized; Interventional; Design type: Process of Care, Drug, Other

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
See additional files

Health condition(s) or problem(s) studied
Organ transplantation

Interventions
This is a multi-centre, single-blind prospective, group sequential, randomised controlled trial. Randomisation will be in a 1:1 ratio and will be stratified according to whether the donorwas receivingstatin therapy at ICU admission.

Setting
ICUs within Level 1 or 2 donating hospitals: defined as a mean number of donors per year > 6 by NHS Blood and Transplant.

Screening
Adult organ donors will be identified by the Specialist Nurses in Organ Donation (SNODs). After they have been through the organ donation consent process with the donor family, they will go through the study-specific consent. The SNODs will complete an eligibility checklist which will be countersigned by the prescribing ICU doctor if the patient is randomised to receive the intervention. No screening logs will be completed.

Randomisation
Following study-specific consent, participants will be randomised using an online randomisation service, called SealedEnvelope, and given a unique Randomisation Number. The treatment allocation will also be provided.

Treatment
The study treatment is 80 mg simvastatin in addition to protocolised standard care. This will be compared to protocolised standard care alone. If randomised to receive the intervention, this will be prescribed by an ICU doctor and issued from hospital stock. The tablet will be crushed, mixed with 20 ml sterile water (hospital stock) and administered via nasogastric tube. Nasogastric tubes are already in place for 80% of organ donors but if this is not already in place, this will be required.

Follow up
Although there will be some intervention and donor data collected by the research team onto an eCRF, most of the data from the donors, and all recipient data, is already collected as part of standard care on the UK Transplant Registry. No additional information or samples will be needed from recipients.

Safety reporting
Serious adverse events will be reported to the REC within 15 days of the clinical team becoming aware. Due to the low-risk intervention and complex patient population, serious adverse events that need reporting will be those assessed by the PI as being related to the study and unexpected. The researchers will also record events that progress to the loss of capacity to donate as a result of the study procedure.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Simvastatin

Primary outcome measure
Updated primary outcome measure as of 01/05/2024:
The primary outcome measure is a composite outcome of death, cardiac mechanical circulatory support or renal replacement therapy within the first 30 days post heart transplant

Previous primary outcome measure:
Composite of death, cardiac mechanical circulatory support or renal replacement therapy, determined by the recipient status on the UK Transplant Registry (UKTR) at 30 days

Secondary outcome measures
1. Organ utilisation rate, measured by the proportion of organs offered that were transplanted for each organ separately and based on the records held by the UK Transplant Registry (UKTR) during the 60-month trial duration, records completed at 30-days or at initial discharge post-transplant whichever is sooner
2. Graft survival for all transplanted organs, based on the records held by the UKTR, at 30 days, 3 months and 12 months
3. Patient survival, determined by status on the UKTR, at 30 days, 3 months and 12 months
4. Length of ITU stay, measured by the number of days the patient was on ITU, based on the records held by the UKTR from the point of transplant to discharge from ITU at discharge from transplant admission
5. Length of hospital stay, measured by the number of days the patient was in hospital, based on the records held by the UKTR excluding kidney recipients at from the point of transplant to discharge from hospital at discharge from transplant admission
6. Proportion of heart recipients requiring mechanical circulatory support up to 30 days, based on the records held by the UKTR
7. Proportion of cardiac recipients requiring renal replacement therapy up to 30 days, based on the records held by the UKTR
8. Patient survival for heart recipients, measured by their status on the UKTR, at 30 days
9. Number of treated rejection episodes for each organ, based on records held by the UKTR, at 3 and 12 months
10. Estimated glomerular filtration rate for kidney recipients, calculated using the Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) equation (2009) from data held by the UKTR at 12 months
11. Proportion of kidney recipients with delayed graft function, defined as the need for dialysis in the first 7 days, based on records held by the UKTR
12. Number of days liver recipients spent ventilated, based on records held by the UKTR at 30 days or at initial discharge post-transplant whichever is sooner
13. Proportion of liver recipients with individual post-operative complications, measured by indicators recording the presence or absence of hepatic artery thrombosis, portal vein thrombosis, inferior vena cava (IVC)/hepatic vein occlusion, haemorrhage requiring reoperation, biliary tract leaks, biliary tract stricture requiring intervention as recorded by the UKTR at 30-days or at initial discharge post-transplant whichever is sooner
14. For liver recipients, the levels of serum creatinine (µmol/), bilirubin (µmol/) and alkaline phosphatase (IU/L) at 12 months, based on the UKTR records
15. FEV1 in lung recipients based on records held in the UKTR and measured in both absolute

terms in litres, from the two best recent measurements as well as % predicted1 as measured at 12 months
16. Proportion of pancreas recipients (including simultaneous pancreas-kidney recipients) with initial pancreas graft function, based on records held on the UKTR at 30-days or at initial discharge post-transplant whichever is sooner
17. Number of treated pancreas rejection episodes in pancreas and simultaneous pancreas-kidney recipients at 3 and 12 months based on the UKTR
18. Categorised causes of graft loss in pancreas and simultaneous pancreas-kidney recipients as recorded on the UKTR at 12 months (causes recorded for pancreas graft failure include: vascular thrombosis, infection, bleeding, anastomotic leak, pancreatitis, primary non-function, hyperacute, acute and chronic rejection, preservation/procurement problem, death with functioning graft, patient declined medication)
19. Proportion of pancreas and simultaneous pancreas-kidney recipients with pancreatitis as recorded in the UKTR up to 3 months
20. C-peptide in pancreas islet recipients, measured by meal tolerance test in units of pmol/l, at 3-month follow-up in the UKTR

Overall study start date
01/10/2020

Completion date
30/06/2026

Eligibility

Key inclusion criteria
1. Within a recruiting Intensive Care Unit
2. Patients diagnosed dead using neurological criteria
3. Consent for organ donation in place, as defined by the Human Tissue Act and accompanying legislation and Codes of Practice
4. Study-specific consent from the donor family

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 2600; UK Sample Size: 2600

Key exclusion criteria

1. Aged <18 years
2. Planned donation after cessation of circulation (DCD)
3. Known donor allergic hypersensitivity to simvastatin

Date of first enrolment
14/09/2021

Date of final enrolment
13/09/2025

Locations

Countries of recruitment
England

Northern Ireland

Scotland

United Kingdom

Wales

Study participating centre
Aberdeen Royal Infirmary
Foresterhill Health Campus
Foresterhill Rd
Aberdeen
United Kingdom
AB25 2ZN

Study participating centre
Royal Gwent Hospital
Cardiff Rd
Newport
United Kingdom
NP20 2UB

Study participating centre
Monklands District General Hospital
Monkscourt Ave
Airdrie
United Kingdom
ML6 0JS

Study participating centre
Hairmyres Hospital
218 Eaglesham Rd
East Kilbride
Glasgow
United Kingdom
G75 8RG

Study participating centre
Wishaw General Hospital
50 Netherton St
Wishaw
United Kingdom
ML2 0DP

Study participating centre
William Harvey Hospital
Kennington Rd
Willesborough
Ashford
United Kingdom
TN24 0LZ

Study participating centre
Kent and Canterbury Hospital
Ethelbert Rd
Canterbury
United Kingdom
CT1 3NG

Study participating centre
Queen Elizabeth the Queen Mother Hospital
Ramsgate Rd
Margate
United Kingdom
CT9 4AN

Study participating centre

University Hospital Ayr
Dalmellington Rd
Ayr
United Kingdom
KA6 6DX

Study participating centre
University Hospital Crosshouse
Kilmarnock Rd
Crosshouse
Kilmarnock
United Kingdom
KA2 0BE

Study participating centre
John Radcliffe Hospital
Headley Way
Headington
Oxford
United Kingdom
OX3 9DU

Study participating centre
Ysbyty Gwynedd
Penrhosgarnedd
Bangor
United Kingdom
LL57 2PW

Study participating centre
Glan Clwyd Hospital
Rhuddlan Rd
Bodelwyddan
Rhyl
United Kingdom
LL18 5UJ

Study participating centre
Wrexham Maelor Hospital
Croesnewydd Rd
Wrexham

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LL13 7TD

Study participating centre
Barnet Hospital
Wellhouse Ln
Barnet
United Kingdom
EN5 3DJ

Study participating centre
Royal Free Hospital
Pond St
London
United Kingdom
NW3 2QG

Study participating centre
Royal United Hospital
Combe Park
Bath
United Kingdom
BA1 3NG

Study participating centre
Belfast City Hospital
Lisburn Rd
Belfast
United Kingdom
BT9 7AB

Study participating centre
Mater Infirmorum Hospital
45-51 Crumlin Rd
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United Kingdom
BT14 6AB

Study participating centre

Royal Victoria Hospital
274 Grosvenor Rd
Belfast
United Kingdom
BT12 6BA

Study participating centre
Queen Elizabeth Hospital Birmingham
Mindelsohn Way
Birmingham
United Kingdom
B15 2TH

Study participating centre
Birmingham City Hospital
Dudley Rd
Birmingham
United Kingdom
B18 7QH

Study participating centre
Sandwell District General Hospital
Lyndon
West Bromwich
United Kingdom
B71 4HJ

Study participating centre
Royal Blackburn Hospital
Haslingden Rd
Blackburn
United Kingdom
BB2 3HH

Study participating centre
Blackpool Victoria Hospital
Whinney Heys Rd
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United Kingdom
FY3 8NR

Study participating centre
Royal Bolton Hospital
Minerva Rd
Farnworth
Bolton
United Kingdom
BL4 0JR

Study participating centre
Pilgrim Hospital
Sibsey Rd
Boston
United Kingdom
PE21 9QS

Study participating centre
Lincoln County Hospital
Greetwell Rd
Lincoln
United Kingdom
LN2 5QY

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Royal Bournemouth Hospital
Castle Ln E
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BH7 7DW

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Prince Charles Hospital
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Merthyr Tydfil
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Southmead Hospital
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Royal Derby Hospital
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Study participating centre
Fairfield General Hospital
Rochdale Old Rd
Bury
United Kingdom
BL9 7TD

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Portsmouth Rd
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Wexham St
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SL2 4HL

Study participating centre
Addenbrooke's Hospital
Hills Rd
Cambridge

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CB2 0QQ

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University Hospital of Wales,
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CF14 4XW

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St Peter's Hospital
Guildford St
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KT16 0PZ

Study participating centre
Countess of Chester Hospital
Liverpool Rd
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St Richard's Hospital
Spitalfield Ln
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PO19 6SE

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Worthing Hospital
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United Kingdom
BN11 2DH

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Fulwood
Preston
United Kingdom
PR2 9HT

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Colchester Hospital
Turner Rd
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CO4 5JL

Study participating centre
Ipswich Hospital
Heath Rd
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United Kingdom
IP4 5PD

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Hull Royal Infirmary
Anlaby Rd
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University Hospital of North Durham
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Study participating centre
Ninewells Hospital
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Eastbourne District General Hospital
Kings Dr
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Conquest Hospital
The Ridge
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TN37 7RD

Study participating centre
Royal Infirmary of Edinburgh
51 Little France Cres
Old Dalkeith Rd
Edinburgh
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Study participating centre
Western General Hospital
Crewe Rd S
Edinburgh
United Kingdom
EH4 2XU

Study participating centre
St John's Hospital
Livingston
Howden W Rd
Howden
Livingston
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EH54 6PP

Study participating centre
South West Acute Hospital
124 Irvinestown Rd
Enniskillen
United Kingdom
BT74 6DN

Study participating centre
Altnagelvin Area Hospital
Glenshane Rd
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Study participating centre
Medway Maritime Hospital
Windmill Road
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ME7 5NY

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Glasgow Royal Infirmary
84 Castle St

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G4 0SF

Study participating centre
Queen Elizabeth University Hospital
1345 Govan Rd
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Royal Alexandra Hospital
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PA2 9PJ

Study participating centre
Diana Princess of Wales Hospital
Scartho Rd
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DN33 2BA

Study participating centre
Scunthorpe General Hospital
Cliff Gardens
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DN15 7BH

Study participating centre
Calderdale Royal Hospital
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Study participating centre

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Royal Brompton Hospital,
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Study participating centre
Ealing Hospital
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Ilford
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IG3 8YB

Study participating centre
Queen's Hospital
Rom Valley Way
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United Kingdom
RM7 0AG

Study participating centre
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Heath Rd
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Study participating centre
Leeds General Infirmary
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Leeds
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Beckett St
Harehills
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LE1 5WW

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Prescot St
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L7 8XP

Study participating centre
Aintree University Hospital
Lower Ln
Liverpool
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Study participating centre
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Lower Ln
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L9 7LJ

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Charing Cross Hospital
Fulham Palace Rd
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Study participating centre
Hammersmith Hospital
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Study participating centre
Princess Royal University Hospital
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National Hospital for Neurology and Neurosurgery
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University College Hospital
235 Euston Rd
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St Bartholomew's Hospital
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EC1A 7BE

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The Royal London Hospital
Whitechapel Rd
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Study participating centre
Whipps Cross Hospital
Whipps Cross Road
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E11 1NR

Study participating centre
St George's Hospital
Blackshaw Rd
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SW17 0QT

Study participating centre
St Thomas' Hospital
Westminster Bridge Rd
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Study participating centre
Queen Elizabeth Hospital
Stadium Rd
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Study participating centre
University Hospital Lewisham
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United Kingdom
SE13 6LH

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Luton & Dunstable University Hospital
Lewsey Rd
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United Kingdom
LU4 0DZ

Study participating centre
Manchester Royal Infirmary
Oxford Rd
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Study participating centre
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Worcestershire Royal Hospital
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Scarborough General Hospital,
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YO12 6QL

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YO31 8HE

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Northern General Hospital
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S10 2JF

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Southampton General Hospital
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Great Western Hospital
Marlborough Rd
Swindon
United Kingdom
SN3 6BB

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WD18 0HB

Study participating centre
New Cross Hospital
Wolverhampton Rd
Heath Town
Wolverhampton
United Kingdom
WV10 0QP

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Morriston Hospital
Heol Maes Eglwys
Cwmrhydyceirw
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United Kingdom
SA6 6NL

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South Tyneside District Hospital
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South Shields
United Kingdom
NE34 0PL

Study participating centre
Sunderland Royal Hospital
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Study participating centre
Basildon
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Nethermayne
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Study participating centre

Gloucestershire Royal Hospital
Great Western Road
Gloucester
United Kingdom
GL1 3NN

Study participating centre
Cheltenham General Hospital
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Cheltenham
United Kingdom
GL53 7AN

Study participating centre
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Lurgan Rd
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United Kingdom
BT63 5QQ

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Stoke Mandeville Hospital
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HP21 8AL

Study participating centre
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Study participating centre
Royal Cornwall Hospitals NHS Trust
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TR1 3LJ

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Pinderfields General Hospital
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TS24 9AH

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Royal Berkshire Hospital
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Reading
United Kingdom
RG1 5AN

Study participating centre
Chesterfield Royal Hospital NHS Foundation Trust
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Calow
Chesterfield
United Kingdom
S44 5BL

Study participating centre
Doncaster & Bassetlaw Hospitals
Doncaster Royal Infirmary
Thorne Road
Doncaster
United Kingdom
DN2 5LT

Study participating centre
Doncaster & Bassetlaw Hospitals
Doncaster Royal Infirmary
Thorne Road
Doncaster
United Kingdom
DN2 5LT

Study participating centre
Withybush General Hospital
Fishguard Road
Haverfordwest
United Kingdom
SA61 2PZ

Study participating centre
West Wales General Hospital
Dolgwili Road
Carmarthen
United Kingdom
SA31 2AF

Study participating centre
Bronglais General Hospital
Bronglais Hospital
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Aberystwyth
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SY23 1ER

Study participating centre
Cumberland Infirmary
Newtown Road
Carlisle
United Kingdom
CA2 7HY

Study participating centre

West Cumberland Hospital
Homewood
Hensingham
Whitehaven
United Kingdom
CA28 8JG

Study participating centre
Taunton
Musgrove Park Hospital
Taunton
United Kingdom
TA1 5DA

Study participating centre
Forth Valley Royal Hospital
Stirling Road
Larbert
United Kingdom
FK5 4WR

Study participating centre
Maidstone
Maidstone Hospital
Hermitage Lane
Maidstone
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ME16 9QQ

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Tunbridge Wells Hospital
The Tunbridge Wells Hospital
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Tunbridge Wells
United Kingdom
TN2 4QJ

Study participating centre
Raigmore Hospital
Old Perth Rd

Inverness
United Kingdom
IV2 3UJ

Study participating centre
Royal Shrewsbury Hospital
Mytton Oak Road
Shrewsbury
United Kingdom
SY3 8XQ

Sponsor information

Organisation
Newcastle upon Tyne Hospitals NHS Foundation Trust

Sponsor details
c/o Rebecca Johnson
Regulatory Compliance Team
Newcastle Joint Research Office
Level 1, Regent Point
Regent Farm
Newcastle-Upon-Tyne
England
United Kingdom
NE3 3HD
+44 (0)191 282 4454
tnu-tr.sponsormanagement@nhs.net

Sponsor type
Hospital/treatment centre

Website
http://www.newcastle-hospitals.org.uk/

ROR
https://ror.org/05p40t847

Funder(s)

Funder type
Government

Funder Name
NIHR Evaluation, Trials and Studies Co-ordinating Centre (NETSCC); Grant Codes: NIHR131124

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal

Intention to publish date
30/06/2027

Individual participant data (IPD) sharing plan
Access to the final dataset for additional analyses will be permitted with the agreement of the Trial Steering Committee. Participant-level data will be held by NHS Blood and Transplant.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	For organ donor's relative version 11	11/06/2021	04/05/2023	No	Yes
Participant information sheet	For organ recipient version 10	12/04/2021	04/05/2023	No	Yes
Protocol (other)	v20	07/12/2022	04/05/2023	No	No
Protocol file	version 20	07/12/2022	04/05/2023	No	No
HRA research summary			28/06/2023	No	No
Protocol article		18/09/2024	20/09/2024	Yes	No