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Statins for improving organ outcome in transplantation

Submission date	**Recruitment status**	[X] Prospectively registered
09/07/2021	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
03/08/2021	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
11/11/2025	Surgery	[_] Record updated in last year

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?
Ashley Foster, SIGNET@nhsbt.nhs.uk

Contact information

Type(s)
Scientific

Contact name
None Ashley Foster

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Additional identifiers

Integrated Research Application System (IRAS)
288722

Central Portfolio Management System (CPMS)

49404

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

Primary study design
Interventional

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

Study type(s)
Treatment

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(s)
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

Key secondary outcome(s)
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

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

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 Years

Upper age limit
100 Years

Sex
All

Total final enrolment
1694

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
United Kingdom

England

Northern Ireland

Scotland

Wales

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

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

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

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

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

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

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

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

Study participating centre
University Hospital Ayr
Dalmellington Rd
Ayr
Scotland
KA6 6DX

Study participating centre
University Hospital Crosshouse
Kilmarnock Rd
Crosshouse
Kilmarnock
Scotland
KA2 0BE

Study participating centre
John Radcliffe Hospital
Headley Way

Headington
Oxford
England
OX3 9DU

Study participating centre
Ysbyty Gwynedd
Penrhosgarnedd
Bangor
Wales
LL57 2PW

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

Study participating centre
Wrexham Maelor Hospital
Croesnewydd Rd
Wrexham
Wales
LL13 7TD

Study participating centre
Barnet Hospital
Wellhouse Ln
Barnet
England
EN5 3DJ

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

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

Study participating centre
Belfast City Hospital
Lisburn Rd
Belfast
Northern Ireland
BT9 7AB

Study participating centre
Mater Infirmorum Hospital
45-51 Crumlin Rd
Belfast
Northern Ireland
BT14 6AB

Study participating centre
Royal Victoria Hospital
274 Grosvenor Rd
Belfast
Northern Ireland
BT12 6BA

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

Study participating centre
Birmingham City Hospital
Dudley Rd
Birmingham

England
B18 7QH

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

Study participating centre
Royal Blackburn Hospital
Haslingden Rd
Blackburn
England
BB2 3HH

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

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

Study participating centre
Pilgrim Hospital
Sibsey Rd
Boston
England
PE21 9QS

Study participating centre
Lincoln County Hospital
Greetwell Rd
Lincoln
England
LN2 5QY

Study participating centre
Royal Bournemouth Hospital
Castle Ln E
Bournemouth
England
BH7 7DW

Study participating centre
Princess of Wales Hospital
Coity Rd
Bridgend
Wales
CF31 1RQ

Study participating centre
Prince Charles Hospital
Gurnos Rd
Merthyr Tydfil
Wales
CF47 9DT

Study participating centre
Royal Glamorgan Hospital
Ynysmaerdy
Pontyclun
Wales
CF72 8XR

Study participating centre
Royal Sussex County Hospital
Barry Building
Eastern Rd

Brighton
England
BN2 5BE

Study participating centre
Princess Royal Hospital
Lewes Rd
Haywards Heath
England
RH16 4EX

Study participating centre
Bristol Royal Infirmary
Upper Maudlin St
Bristol
England
BS2 8HW

Study participating centre
Southmead Hospital
Southmead Rd
Bristol
England
BS10 5NB

Study participating centre
Royal Derby Hospital
Uttoxeter Rd
Derby
England
DE22 3NE

Study participating centre
Fairfield General Hospital
Rochdale Old Rd
Bury
England
BL9 7TD

Study participating centre
Royal Oldham Hospital
Rochdale Rd
Oldham
England
OL1 2JH

Study participating centre
Frimley Park Hospital
Portsmouth Rd
Frimley
Camberley
England
GU16 7UJ

Study participating centre
Wexham Park Hospital
Wexham St
Slough
England
SL2 4HL

Study participating centre
Addenbrooke's Hospital
Hills Rd
Cambridge
England
CB2 0QQ

Study participating centre
University Hospital of Wales,
Heath Park Way
Cardiff
Wales
CF14 4XW

Study participating centre
St Peter's Hospital
Guildford St
Lyne
Chertsey

England
KT16 0PZ

Study participating centre
Countess of Chester Hospital
Liverpool Rd
Chester
England
CH2 1UL

Study participating centre
St Richard's Hospital
Spitalfield Ln
Chichester
England
PO19 6SE

Study participating centre
Worthing Hospital
Lyndhurst Rd
Worthing
England
BN11 2DH

Study participating centre
Royal Preston Hospital
Sharoe Green Ln
Fulwood
Preston
England
PR2 9HT

Study participating centre
Colchester Hospital
Turner Rd
Colchester
England
CO4 5JL

Study participating centre
Ipswich Hospital
Heath Rd
Ipswich
England
IP4 5PD

Study participating centre
Hull Royal Infirmary
Anlaby Rd
Hull
England
HU3 2JZ

Study participating centre
University Hospital Coventry & Warwickshire
Clifford Bridge Rd
Coventry
England
CV2 2DX

Study participating centre
Darlington Memorial Hospital
Hollyhurst Rd
Darlington
England
DL3 6HX

Study participating centre
University Hospital of North Durham
North Rd
Durham
England
DH1 5TW

Study participating centre
Ninewells Hospital
James Arrott Dr
Dundee
Scotland
DD2 1SG

Study participating centre
Eastbourne District General Hospital
Kings Dr
Eastbourne
England
BN21 2UD

Study participating centre
Conquest Hospital
The Ridge
Saint Leonards-on-Sea
England
TN37 7RD

Study participating centre
Royal Infirmary of Edinburgh
51 Little France Cres
Old Dalkeith Rd
Edinburgh
Scotland
EH16 4SA

Study participating centre
Western General Hospital
Crewe Rd S
Edinburgh
Scotland
EH4 2XU

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

Study participating centre
South West Acute Hospital
124 Irvinestown Rd
Enniskillen
Northern Ireland
BT74 6DN

Study participating centre
Altnagelvin Area Hospital
Glenshane Rd
Londonderry
Northern Ireland
BT47 6SB

Study participating centre
Medway Maritime Hospital
Windmill Road
Gillingham
England
ME7 5NY

Study participating centre
Glasgow Royal Infirmary
84 Castle St
Glasgow
Scotland
G4 0SF

Study participating centre
Queen Elizabeth University Hospital
1345 Govan Rd
Glasgow
Scotland
G51 4TF

Study participating centre
Royal Alexandra Hospital
Castlehead
Paisley
Scotland
PA2 9PJ

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

Study participating centre
Scunthorpe General Hospital
Cliff Gardens
Scunthorpe
England
DN15 7BH

Study participating centre
Calderdale Royal Hospital
-
Halifax
England
HX3 0PW

Study participating centre
Huddersfield Royal Infirmary
Acre St
Lindley
Huddersfield
England
HD3 3EA

Study participating centre
Harefield Hospital
Hill End Rd
Harefield
Uxbridge
England
UB9 6JH

Study participating centre

Royal Brompton Hospital,
Sydney St
London
England
SW3 6NP

Study participating centre
Northwick Park Hospital
Watford Rd
Harrow
England
HA1 3UJ

Study participating centre
Ealing Hospital
601 Uxbridge Rd
Southall
England
UB1 3HW

Study participating centre
King George Hospital
Barley Ln
Ilford
England
IG3 8YB

Study participating centre
Queen's Hospital
Rom Valley Way
Romford
England
RM7 0AG

Study participating centre
Ipswich Hospital
Heath Rd
Ipswich
England
IP4 5PD

Study participating centre
Leeds General Infirmary
Great George St
Leeds
England
LS1 3EX

Study participating centre
St James's University Hospital
Beckett St
Harehills
Leeds
England
LS9 7TF

Study participating centre
Glenfield Hospital
Groby Rd
Leicester
England
LE3 9QP

Study participating centre
Leicester Royal Infirmary
Infirmary Square
Leicester
England
LE1 5WW

Study participating centre
Royal Liverpool University Hospital
Prescot St
Liverpool
England
L7 8XP

Study participating centre
Aintree University Hospital
Lower Ln

Liverpool
England
L9 7AL

Study participating centre
The Walton Centre
Lower Ln
Liverpool
England
L9 7LJ

Study participating centre
Charing Cross Hospital
Fulham Palace Rd
London
England
W6 8RF

Study participating centre
Hammersmith Hospital
72 Du Cane Rd
London
England
W12 0HS

Study participating centre
St Mary's Hospital
Praed St
London
England
W2 1NY

Study participating centre
King's College Hospital
Denmark Hill
London
England
SE5 9RS

Study participating centre
Princess Royal University Hospital
Farnborough Common
Orpington
England
BR6 8ND

Study participating centre
National Hospital for Neurology and Neurosurgery
Queen Square
London
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WC1N 3BG

Study participating centre
University College Hospital
235 Euston Rd
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NW1 2BU

Study participating centre
Newham University Hospital
Glen Rd
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England
E13 8SL

Study participating centre
St Bartholomew's Hospital
W Smithfield
London
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EC1A 7BE

Study participating centre
The Royal London Hospital
Whitechapel Rd
London
England
E1 1FR

Study participating centre
Whipps Cross Hospital
Whipps Cross Road
London
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E11 1NR

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

Study participating centre
St Thomas' Hospital
Westminster Bridge Rd
London
England
SE1 7EH

Study participating centre
Queen Elizabeth Hospital
Stadium Rd
London
England
SE18 4QH

Study participating centre
University Hospital Lewisham
Lewisham High St
London
England
SE13 6LH

Study participating centre
Luton & Dunstable University Hospital
Lewsey Rd

Luton
England
LU4 0DZ

Study participating centre
Manchester Royal Infirmary
Oxford Rd
Manchester
England
M13 9WL

Study participating centre
Wythenshawe Hospital
Southmoor Rd
Wythenshawe
Manchester
England
M23 9LT

Study participating centre
The James Cook University Hospital
Marton Rd
Middlesbrough
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TS4 3BW

Study participating centre
Newcastle Freeman Hospital,
Freeman Rd
High Heaton
Newcastle upon Tyne
England
NE7 7DN

Study participating centre
Royal Victoria Infirmary
Queen Victoria Rd
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NE1 4LP

Study participating centre
Northumbria Specialist Emergency Care Hospital
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NE23 6NZ

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Norfolk & Norwich University Hospital
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NR4 7UY

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Nottingham City Hospital
Hucknall Rd
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NG5 1PB

Study participating centre
Queen's Medical Centre
Derby Rd
Lenton
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NG7 2UH

Study participating centre
Derriford Hospital
Derriford Rd
Plymouth
England
PL6 8DH

Study participating centre

Queen Alexandra Hospital
Cosham
Portsmouth
England
PO6 3LY

Study participating centre
Whiston Hospital,
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Prescot
England
L35 5DR

Study participating centre
Alexandra Hospital
Woodrow Dr
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England
B98 7UB

Study participating centre
Worcestershire Royal Hospital
Charles Hastings Way
Worcester
England
WR5 1DD

Study participating centre
Salford Royal Hospital
Stott Ln
Salford
England
M6 8HD

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Scarborough General Hospital,
Woodlands Dr
Scarborough
England
YO12 6QL

Study participating centre
York District Hospital,
Clifton
York
England
YO31 8HE

Study participating centre
Northern General Hospital
Herries Rd
Sheffield
England
S5 7AU

Study participating centre
Royal Hallamshire Hospital
Glossop Rd
Broomhall
Sheffield
England
S10 2JF

Study participating centre
Southampton General Hospital
Tremona Rd
Southampton
England
SO16 6YD

Study participating centre
Lister Hospital
Coreys Mill Ln
Stevenage
England
SG1 4AB

Study participating centre

Royal Stoke University Hospital
Newcastle Rd
Stoke-on-Trent
England
ST4 6QG

Study participating centre
Great Western Hospital
Marlborough Rd
Swindon
England
SN3 6BB

Study participating centre
Watford General Hospital
Vicarage Rd
Watford
England
WD18 0HB

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

Study participating centre
Morriston Hospital
Heol Maes Eglwys
Cwmrhydyceirw
Swansea
Wales
SA6 6NL

Study participating centre
South Tyneside NHS Foundation Trust
South Tyneside District Hospital
Harton Lane
South Shields

England
NE34 0PL

Study participating centre
Sunderland Royal Hospital
Kayll Road
Sunderland
England
SR4 7TP

Study participating centre
Basildon
Basildon Hospital
Nethermayne
Basildon
England
SS16 5NL

Study participating centre
Gloucestershire Royal Hospital
Great Western Road
Gloucester
England
GL1 3NN

Study participating centre
Cheltenham General Hospital
Sandford Road
Cheltenham
England
GL53 7AN

Study participating centre
Craigavon Area Hospital
Lurgan Rd
Craigavon
Northern Ireland
BT63 5QQ

Study participating centre
Stoke Mandeville Hospital
Mandeville Road
Aylesbury
England
HP21 8AL

Study participating centre
Wycombe General Hospital
Queen Alexandra Road
High Wycombe
England
HP11 2TT

Study participating centre
Royal Cornwall Hospitals NHS Trust
Royal Cornwall Hospital
Treliske
Truro
England
TR1 3LJ

Study participating centre
Pinderfields and Pontefract Hospitals NHS Trust
Rowan House
Pinderfields General Hospital
Aberford Road
Wakefield
England
WF1 4EE

Study participating centre
North Tees and Hartlepool NHS Foundation Trust
University Hospital of Hartlepool
Holdforth Road
Hartlepool
England
TS24 9AH

Study participating centre

Royal Berkshire Hospital
Royal Berkshire Hospital
London Road
Reading
England
RG1 5AN

Study participating centre
Chesterfield Royal Hospital NHS Foundation Trust
Chesterfield Road
Calow
Chesterfield
England
S44 5BL

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

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

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

Study participating centre
West Wales General Hospital
Dolgwili Road

Carmarthen
Wales
SA31 2AF

Study participating centre
Bronglais General Hospital
Bronglais Hospital
Caradoc Road
Aberystwyth
Wales
SY23 1ER

Study participating centre
Cumberland Infirmary
Newtown Road
Carlisle
England
CA2 7HY

Study participating centre
West Cumberland Hospital
Homewood
Hensingham
Whitehaven
England
CA28 8JG

Study participating centre
Taunton
Musgrove Park Hospital
Taunton
England
TA1 5DA

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

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

Study participating centre
Tunbridge Wells Hospital
The Tunbridge Wells Hospital
Tonbridge Road
Pembury
Tunbridge Wells
England
TN2 4QJ

Study participating centre
Raigmore Hospital
Old Perth Rd
Inverness
Scotland
IV2 3UJ

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

Sponsor information

Organisation
Newcastle upon Tyne Hospitals NHS Foundation Trust

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

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?
Protocol article		18/09/2024	20/09/2024	Yes	No
HRA research summary			28/06/2023	No	No
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
Study website	Study website	11/11/2025	11/11/2025	No	Yes