Statins for improving organ outcome in transplantation

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

Contact details

NHS Blood and Transplant Clinical Trials Unit Long Road Cambridge United Kingdom CB2 0PT +44 (0)1223 588 016 SIGNET@nhsbt.nhs.uk

Additional identifiers

Clinical Trials Information System (CTIS)Nil known

Integrated Research Application System (IRAS)

ClinicalTrials.gov (NCT)

Nil known

Protocol serial number

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

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 (μ mol/), bilirubin (μ mol/) 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 pancreaskidney 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 BA13NG

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

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 England WC1N 3BG

Study participating centre University College Hospital

235 Euston Rd London England NW1 2BU

Study participating centre Newham University Hospital

Glen Rd London England E13 8SL

Study participating centre St Bartholomew's Hospital

W Smithfield

London England 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 England 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 England 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 Newcastle upon Tyne England NE1 4LP

Study participating centre Northumbria Specialist Emergency Care Hospital

Northumbria Way Cramlington England NE23 6NZ

Study participating centre Norfolk & Norwich University Hospital

Colney Ln Colney Norwich England NR4 7UY

Study participating centre Nottingham City Hospital

Hucknall Rd Nottingham England NG5 1PB

Study participating centre Queen's Medical Centre

Derby Rd Lenton Nottingham England 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,

Warrington Rd Rainhill Prescot England L35 5DR

Study participating centre Alexandra Hospital

Woodrow Dr Redditch 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

Study participating centre 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
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	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