

Hypothermic oxygenated pancreas perfusion - the HOPP study

Submission date 23/02/2026	Recruitment status No longer recruiting	☒ Prospectively registered ☐ Protocol
Registration date 02/03/2026	Overall study status Ongoing	☐ Statistical analysis plan ☐ Results
Last Edited 02/03/2026	Condition category Surgery	☐ Individual participant data ☒ Record updated in last year

Plain English summary of protocol

Background and study aims

Pancreas transplantation is an effective treatment for patients with the most severe complications of diabetes. It improves quality of life and life expectancy by returning blood sugar levels to normal and removing the need for insulin. Most pancreas transplants are performed at the same time as a kidney transplant for patients with kidney failure due to diabetes.

When a donor pancreas is removed from the body, it is stored in specialist fluid in an icebox. This simple method slows down cell activity and reduces the need for oxygen and energy. Recent clinical trials in kidney and liver transplantation have shown that continuously pumping the organ with cold preservation fluid enriched with oxygen provides improved protection and better clinical outcomes. This technique has increased donor organ utilisation (defined as the proportion of organs donated that result in a transplant) but has not been tested in pancreas transplantation. This study will investigate the application of the above-mentioned technique in pancreas transplantation.

Who can participate?

Patients aged 18 years and over who are receiving a simultaneous pancreas and kidney transplant in Oxford

What does the study involve?

The donor organs will be transported from the donor hospital as usual in an icebox. While the kidney is being transplanted, the pancreas will be pumped with oxygenated fluid for 2 hours. The pancreas will then be transplanted as standard. Outcomes in these 30 patients will be compared to 60 recent patients who have had the same type of transplant without pumping of oxygenated fluid. Outcomes will be assessed, including the function and survival of both the pancreas and kidney, post-transplant complications (particularly any inflammation of the pancreas), the need for additional surgery, and the length of hospital stay.

What are the possible benefits and risks of participating?

This research has the potential to reduce injury to the donor pancreas, increasing the number of pancreases safely and successfully used for transplant.

Where is the study run from?

The study is run by NHS Blood and Transplant Clinical Trials Unit and the University of Oxford (UK)

When is the study starting and how long is it expected to run for?

March 2026 to December 2026

Who is funding the study?

National Institute for Health and Care Research (NIHR) (UK)

Who is the main contact?

HOPP@nhsbt.nhs.uk

Contact information

Type(s)

Scientific, Public, Principal investigator

Contact name

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Contact details

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Additional identifiers

Integrated Research Application System (IRAS)

334198

Central Portfolio Management System (CPMS)

61042

Study information

Scientific Title

Oxygenated hypothermic machine perfusion in pancreas preservation for transplantation, a Phase I safety and feasibility trial

Acronym

HOPP

Study objectives

Ethics approval required

Ethics approval required

Ethics approval(s)

Approved 27/01/2026, North West - Greater Manchester South Research Ethics Committee (2 Redman Place Stratford, London, E20 1JQ, United Kingdom; Not provided; gmsouth.rec@hra.nhs.uk), ref: 25/NW/0256

Primary study design

Interventional

Allocation

Non-randomized controlled trial

Masking

Open (masking not used)

Control

Historical

Assignment

Single

Purpose

Treatment

Study type(s)**Health condition(s) or problem(s) studied**

Simultaneous pancreas-kidney transplants

Interventions

120 minutes of oxygenated hypothermic machine perfusion of the pancreas graft at the end of the cold ischaemia time.

The study will recruit 30 patients who are receiving a simultaneous pancreas and kidney transplant in Oxford. The donor organs will be transported from the donor hospital as usual in an icebox. While the kidney is being transplanted, the pancreas will be pumped with oxygenated fluid for 2 hours. The pancreas will then be transplanted as standard. Outcomes in these 30 patients will be compared to 60 recent patients who have had the same type of transplant without pumping of oxygenated fluid. Outcomes will be assessed including the function and survival of both pancreas and kidney, post-transplant complications (particularly any inflammation of the pancreas), the need for additional surgery and the length of hospital stay.

Intervention Type

Device

Phase

Phase I

Drug/device/biological/vaccine name(s)

VitaSmart

Primary outcome(s)

1. Safety and feasibility of end-ischaemic HMPO2 of pancreas grafts prior to transplantation in clinical practice, measured using pancreas graft survival, defined as the absence of insulin requirement at 90 days postoperatively

Key secondary outcome(s)

1. Proportion of perfused pancreases transplanted (organ utilisation), measured at the time of the operation
2. Proportion of patients with pancreas graft intra-vascular thrombosis (detected on CT scan, day 2-10 post-op) requiring anticoagulation during inpatient stay
3. Proportion of patients with early kidney graft loss, defined as surgical removal of the kidney during the 3-month follow-up period
4. Proportion of patients with post-transplantation graft pancreatitis, defined as evidence of pancreatitis on contrast-enhanced CT scan of the abdomen (performed between day 2 and 10 post-op).
5. Proportion of patients with at least one clinically suspected & treated episode of acute rejection of pancreas graft during the 3-month follow-up period
6. Patient survival at 90 days estimated using the Kaplan-Meier method
7. Median length of hospital and ICU stay postoperatively (a surrogate marker for burden of postoperative complications)
8. Proportion of patients with ureteric, bowel, and vascular complications during the 3-month follow-up period
9. Median number of interventions per patient (surgical/endoscopic/radiological) in the first 30 days after transplantation
10. Proportion of patients with at least one re-admission during the 3-month follow-up period
11. Proportion of patients with at least one infection (defined as a clinically diagnosed and treated infection) during the 3-month follow-up period
12. Mean change in full blood count, serum glucose, serum C-reactive protein (CRP), serum amylase and lipase during inpatient stay. Mean change will be estimated using linear regression.
13. Mean/median full blood count, serum glucose, serum C-reactive protein (CRP), serum amylase and lipase at 1-month and 3-month follow-up visits
14. Mean change in blood glucose (point-of-care) during inpatient stay. Mean change will be estimated using linear regression
15. Mean change in drain amylase (when available) during inpatient stay. Mean change will be estimated using linear regression
16. Mean/median* glycated haemoglobin (HbA1C) at 90 days.
17. Proportion of patients with normal, impaired glucose tolerance or diabetic oral glucose tolerance test (OGTT) results at discharge and at 90 days (These categories are normal if fasting is under 6 mmol/L and at 2 hours is under 7.8 mmol/L, impaired glucose tolerance if fasting is 6.0 to 6.9 mmol/L and at 2 hours is 7.9 to 11.0 mmol/L, or diabetic if fasting is over or equal to 7.0 mmol/L and/or at 2 hours is over or equal to 11.1 mmol/l)
18. Proportion of patients with 90-day graft loss related to transplant intravascular thrombosis
19. Proportion of patients with delayed kidney graft function (DGF), defined as the need for dialysis in the first week after transplantation
20. Proportion of patients with acute kidney rejection in the first 90 days after transplantation, defined as an episode of rejection (Banff 1a or greater) confirmed by graft biopsy
21. Mean/median* serum creatinine at 90 days

22. Kidney graft function, defined as mean estimated glomerular filtration rate (eGFR) at 90 days in ml/min/1.73 m² using the CKD-EPI formula

23. During HMPO2 the following will be recorded to explore possible viability markers. As this is novel data, only available for the HMPO2 group, a range of descriptive statistics and plots will be used to explore the data over time.

23.1. Perfusate flow in the circuit as recorded by the investigator

23.2. Pancreatic resistance as recorded by the investigator

23.3. Proportion of pancreases with no oedema, mild, moderate and severe oedema using macroscopic oedema scale

23.4. Markers of damage in the perfusate measured at 15-minute intervals during perfusion:

23.4.1. Amylase

23.4.2. Lipase

23.4.3. Cell-free DNA (cfDNA)

Completion date

31/12/2026

Eligibility

Key inclusion criteria

Organ offer (donor liver) criteria:

1. Simultaneous pancreas and kidney from deceased donors, including both Donation after Circulatory Death (DCD) and Donation after Brain Death (DBD) donors
2. Accepted for transplantation according to local criteria
3. Cold ischaemia time (CIT), on arrival to recipient centre, no greater than 10 hours
4. Both donor organs, kidney and pancreas, transported in static cold storage (SCS) prior to the start of oxygenated hypothermic machine perfusion (HMPO2)
5. Donor/family/next of kin consent for research

Recipient criteria:

1. Participant is able to give informed consent for participation in the trial
2. Participant has had at least 24 hours to consider written information sent to them
3. 18 years or older
4. On waiting list for simultaneous pancreas-kidney transplantation at Oxford Transplant Centre
5. Able to comply with all study requirements (in the opinion of the investigator or deputy)
6. Fit to proceed with simultaneous pancreas-kidney transplantation

Healthy volunteers allowed

No

Age group

Mixed

Lower age limit

18 Years

Upper age limit

100 Years

Sex

All

Total final enrolment

0

Key exclusion criteria

Organ offer (donor liver) criteria:

1. Donor organs accepted for pancreas-only transplants (pancreas after kidney or pancreas transplant alone)
2. Donors subjected to Normothermic Regional Perfusion (NRP)

Recipient criteria:

1. Participation in an investigational study likely to affect interpretation of the trial data.
2. Recipients of pancreas-alone or pancreas-after-kidney transplants will be excluded
3. Other significant disease or disorder, which, in the opinion of the Investigator, may: (i) put the participant at risk by participating in the study; (ii) affect the participant's ability to participate in the study

Date of first enrolment

23/03/2026

Date of final enrolment

30/09/2026

Locations**Countries of recruitment**

United Kingdom

England

Study participating centre

Churchill Hospital

Old Road

Headington

Oxford

England

OX3 7LE

Sponsor information**Organisation**

University of Oxford

ROR

<https://ror.org/052gg0110>

Funder(s)

Funder type

Funder Name

National Institute for Health and Care Research

Alternative Name(s)

National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not expected to be made available