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The OrQA-UK (Organ Quality Assessment) trial: testing a new artificial intelligence tool to help increase the use of donated livers in the UK

Submission date 19/05/2026	**Recruitment status** Not yet recruiting	[X] Prospectively registered [_] Protocol
Registration date 29/05/2026	**Overall study status** Ongoing	[_] Statistical analysis plan [_] Results
Last Edited 29/05/2026	**Condition category** Other	[_] Individual participant data [X] Record updated in last year

Plain English summary of protocol

Background and study aims
Organ transplants have transformed the prospects for patients with organ failure, but there are fewer organs available to transplant than people needing them. Those available are under-used because of concerns about quality.
Liver quality can be assessed by sending a biopsy to a laboratory, but this costs time and money. Photographs of organs are often used as part of decision-making through the TransplantPath NHS online platform, which is used for transplant administration, but image quality is varied and open to error. This means that transplant services rely on surgeons taking out the donor organs to judge their quality and health by how they look and feel. Transplant surgeons will often play it safe, for example by overestimating the amount of fat in a liver. This cautious approach means that some good quality organs may not be used.
Our team has developed an Artificial Intelligence-powered tool (OrQA, Organ Quality Assessment) that can standardise an organ photograph by accurately assessing the organ's quality and providing an OrQA quality score. The aim of the OrQA-UK clinical trial is to show that the OrQA-Liver (OrQA-L) quality score can assist transplant surgeons in evaluating the quality of donated livers, and reduce the rate at which donated livers are not used by 25%. This could mean 60 extra liver transplants taking place a year.

Who can participate?
This trial does not recruit participants, it enrols donor livers as the trial entity

What does the study involve?
In this clinical trial, photographs of livers will be randomly allocated to either having an OrQA-L quality score displayed with them, or not. The scores will be displayed alongside the liver images for transplant surgeons to see. This will mean we can assess scientifically if the OrQA-L quality score is helpful to surgeons, while still ensuring patient safety.

What are the possible benefits and risks of participating?
N/A, participants are not directly recruited into this study

Where is the study run from?
The study is Sponsored by Newcastle Upon Tyne Hospitals NHSFT who have delegated trial management to the NHS Blood & Transplant Clinical Trials Unit based in Cambridge

When is the study starting and how long is it expected to run for?
Expected to start in August 2026 until January 2029

Who is funding the study?
NIHR Invention for Innovation Programme

Who is the main contact?
The OrQA-UK trial team at NHSBT Clinical Trials Unit, OrQATrial@nhsbt.nhs.uk

Contact information

Type(s)
Public, Scientific

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Additional identifiers

Integrated Research Application System (IRAS)
354517

Central Portfolio Management System (CPMS)
64647

National Institute for Health and Care Research (NIHR)
208448

Study information

Scientific Title
OrQA-UK (Organ Quality Assessment): novel clinical trial of an AI enabled photograph assessment tool to improve organ utilisation in the United Kingdom

Acronym
OrQA-UK trial

Study objectives
Primary Objective: To compare the non-use rate of livers between the control arm and intervention arm, which have the OrQA-L score displayed
Secondary Objective: To assess the quality of the graft and transplant outcome
Exploratory Objective: To compare the two arms using data obtained from livers which were perfused using ex-situ machine perfusion

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 15/05/2026, Yorkshire & The Humber - Sheffield Research Ethics Committee (NHS Blood and Transplant Blood Donor Centre, Holland Drive, Newcastle upon Tyne, NE2 4NQ, United Kingdom; +44 207 104 8010; sheffield.rec@hra.nhs.uk), ref: 26/YH/0086

Primary study design
Interventional

Allocation
Randomized controlled trial

Masking
Open (masking not used)

Control
Active

Assignment
Parallel

Purpose
Diagnostic, Screening

Study type(s)
Treatment

Health condition(s) or problem(s) studied
AI enabled photograph assessment tool to improve liver organ use in the United Kingdom

Interventions
Collection of follow up data from the NHSBT UK Transplant Registry, NHSBT statistician

Intervention Type
Other

Primary outcome(s)
1. Proportion of livers which were not transplanted measured using Data taken from the NHSBT TransplantPath platform at Between retrieval and transplantation/non-use

Key secondary outcome(s))
Measured using Data taken from the UK Transplant Registry at Between transplantation and 3 months post-transplant:
1. Proportion of recipients alive
2. Proportion of recipients with graft functioning at 3 months post-transplant
3. Proportion of recipients experiencing primary non-function
4. Proportion of recipients experiencing renal impairment
5. Proportion of recipients requiring reoperation due to haemorrhage
6. Proportion of recipients experiencing hepatic artery thrombosis
7. Proportion of recipients experiencing biliary tract leaks
8. Proportion of recipients experiencing biliary tract strictures requiring intervention
9. Proportion of recipients experiencing portal vein thrombosis
10. Proportion of recipients experiencing IVC/hepatic vein occlusion
11. Proportion of recipients experiencing post-operative wound sepsis
12. Proportion of recipients experiencing post-operative fungal infections
13. Mean number of treated rejection episodes since transplant

Completion date
01/01/2029

Eligibility

Key inclusion criteria
1. Donor family consent for research provided and no restrictions against commercial involvement, confirmed in TransplantPath
2. Donor liver with at least one back-bench image, confirmed in TransplantPath
3. Has assigned Donor ODT number, confirmed in TransplantPath
4. Donor type (DCD/DBD) provided, confirmed in TransplantPath
5. Liver image(s) passes OrQA image quality check, confirmed by the OrQA system
6. Liver image(s) passes OrQA liver/non-liver check, confirmed by the OrQA system
7. OrQA-L score completed by the OrQA system

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Total final enrolment
0

Key exclusion criteria
1. Living donor livers, confirmed in TransplantPath
2. Livers not offered through TransplantPath (e.g. Domino), confirmed in TransplantPath

Date of first enrolment
01/08/2026

Date of final enrolment
30/09/2028

Locations

Countries of recruitment
United Kingdom

Study participating centre
This is a decentralised trial and there are no participating centres/sites
-
-
England
-

Sponsor information

Organisation
Newcastle upon Tyne Hospitals NHS Foundation Trust

ROR
https://ror.org/05p40t847

Funder(s)

Funder type

Government

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
Data sharing statement to be made available at a later date