

A study of donor lung perfusion in lung transplantation in United Kingdom

Submission date 06/02/2012	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 06/02/2012	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 24/05/2019	Condition category Respiratory	<input type="checkbox"/> Individual participant data

Plain English summary of protocol
Not provided at time of registration

Study website
<http://www.develop-uk.net>

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

11451; HTA 10/82/01

Study information

Scientific Title

A study of Donor Ex-Vivo Lung Perfusion in United Kingdom lung transplantation (DEVELOP-UK)

Acronym

DEVELOP-UK

Study objectives

The DEVELOP-UK study is designed to investigate the clinical effectiveness and cost effectiveness of a new technology called ex-vivo lung perfusion or EVLP. EVLP is a novel technique in which unusable donor lungs which are functioning poorly or in which function is uncertain, can be carefully assessed and potentially improved for safe use in clinical lung transplantation.

EVLP is performed outside the organ donors or transplant recipients body by connecting the donated lungs to the EVLP system a modified heart-lung bypass machine. The EVLP system warms the lungs to body temperature and pumps a specialised nutrient solution called perfusate through them. At the same time the lungs are ventilated with oxygen by connecting them to a standard intensive care unit ventilator. EVLP provides the opportunity to carefully assess donor lung function over a number of hours before making a decision on their usability for transplantation.

The primary objective of the study is to determine if survival in the first 12 months after lung transplantation in recipients of EVLP assessed and improved donor lungs (treatment group) is not any worse than that in recipients of standard donor lungs (control group).

The secondary objectives are to measure key early clinical outcomes and changes in quality of life (QOL) in the treatment and control groups in their first post-transplant year. This data will be used to decide if EVLP is a cost effective treatment. In addition patients perceptions of EVLP improved donor lungs will be examined in an interview sub-study. Finally we will evaluate which donor factors and EVLP related characteristics are associated with successful donor lung assessment and improvement and with successful outcomes after transplant.

More details can be found at: [http://public.ukcrn.org.uk/Search/StudyDetail.aspx?](http://public.ukcrn.org.uk/Search/StudyDetail.aspx?StudyID=11451)

StudyID=11451 and <http://www.nets.nihr.ac.uk/projects/hta/108201>

Protocol can be found at: http://www.nets.nihr.ac.uk/__data/assets/pdf_file/0006/55770/PRO-10-82-01.pdf

Ethics approval required

Old ethics approval format

Ethics approval(s)

NRES Committee North East Sunderland, 28/11/2011, ref: 11/NE/0342

Study design

Non-randomised interventional trial

Primary study design

Interventional

Secondary study design

Non randomised study

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied

Respiratory disease

Interventions

EVLP reconditioning of lung, The experimental intervention is ex-vivo lung perfusion (EVLP). EVLP is performed outside the donor or recipient body by connecting the lungs to a modified heart-lung bypass circuit which warms the lungs to body temperature and pumps the specialised nutrient solution or 'perfusate' through them.

The standard lung procurement procedure will be followed for donor lungs to be used for EVLP in the study.

Followed up at 12 months

Intervention Type

Other

Phase

Not Applicable

Primary outcome measure

1. Survival during the first 12 months after lung transplantation
2. Non-inferiority of EVLP using standard methods for survival data at each interim analysis time point

Secondary outcome measures

No secondary outcome measures

Overall study start date

01/02/2012

Completion date

30/01/2014

Eligibility

Key inclusion criteria

Trial:

1. Male or female patients
2. Adult patients (aged over 18 years)
3. Patients already on or added to the active waiting list for first lung transplant while the DEVELOP-UK study is in its recruitment phase
4. Patients providing informed consent for participation in the DEVELOP-UK study at the time of study commencement or time of listing for transplant
5. Patients reconfirming informed consent for the DEVELOP-UK study on the day of lung transplant

Qualitative substudy:

1. All patients who are eligible for the DEVELOP-UK trial
2. Patients at Newcastle Hospitals NHS Foundation Trust and Royal Brompton and Harefield NHS Foundation Trust only
3. All patients who consent to the DEVELOP-UK trial as a whole and the qualitative study specifically (regardless of whether they receive a transplant)
4. Male & female participants
5. Lower Age Limit 18 years

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

Planned Sample Size: 408; UK Sample Size: 408

Key exclusion criteria

Trial:

1. Patients aged less than 18 years
2. Patients listed for lung re-transplantation
3. Patients listed for heart-lung transplantation
4. Patients listed for live donor lobar transplant
5. Patients not initially consented or signed EOI form for the DEVELOP-UK study prior to the day of lung transplant
6. Patients not reconfirming consent for the DEVELOP-UK study on the day of lung transplant
7. Patients in the ITU requiring invasive ventilation, ECMO or NovaLung support
8. Patients enrolled in Trials within the preceding 12 months (please discuss with principal and chief investigators)

Qualitative sub-study

All patients who have not consented to the DEVELOP-UK trial from Manchester, Papworth and Birmingham sites.

Date of first enrolment

01/02/2012

Date of final enrolment

30/01/2014

Locations

Countries of recruitment

England

United Kingdom

Study participating centre

Institute of Health and Society

Newcastle Upon Tyne

United Kingdom

NE2 4HH

Sponsor information

Organisation

Newcastle upon Tyne Hospitals NHS Foundation Trust (UK)

Sponsor details

Royal Victoria Infirmary

Leazes Wing

Queen Victoria Road

Newcastle Upon Tyne

England

United Kingdom

NE1 4LP

Sponsor type

Hospital/treatment centre

Website

<http://www.newcastle-hospitals.org.uk/>

ROR

Funder(s)

Funder type

Charity

Funder Name

Cystic Fibrosis Trust (UK)

Alternative Name(s)

Cystic Fibrosis, CF

Funding Body Type

Private sector organisation

Funding Body Subtype

Other non-profit organizations

Location

United Kingdom

Funder Name

Health Technology Assessment Programme

Alternative Name(s)

NIHR Health Technology Assessment Programme, HTA

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

United Kingdom

Results and Publications

Publication and dissemination plan

Not provided at time of registration

Intention to publish date

01/11/2016

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/11/2016		Yes	No
Results article	economic evaluation results	22/05/2019	24/05/2019	Yes	No