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

| Submission date | Recruitment status | [_] Prospectively registered |
|---|---|---|
| 06/02/2012 | No longer recruiting | [_] Protocol |
| **Registration date** | **Overall study status** | [_] Statistical analysis plan |
| 06/02/2012 | Completed | [X] Results |
| **Last Edited** | **Condition category** | [_] Individual participant data |
| 24/05/2019 | Respiratory | |

**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?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

https://ror.org/05p40t847

# 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 |