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UK lung volume reduction trial

Submission date 08/11/2016	**Recruitment status** Recruiting	[ ] Prospectively registered [ ] Protocol
Registration date 09/01/2017	**Overall study status** Ongoing	[ ] Statistical analysis plan [ ] Results
Last Edited 12/10/2022	**Condition category** Respiratory	[ ] Individual participant data [ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Chronic obstructive pulmonary disease (COPD) is the name for a group of lung conditions that cause breathing difficulties. In some patients with emphysema (damage to the air sacs in the lungs), an operation called lung volume reduction surgery is effective at removing the worst affected area of the lung. New techniques have been developed where emphysema can be treated using a fibre-optic camera called a bronchoscope. Studies have shown that using a bronchoscope to place implantable medical devices called endobronchial valves into the airways can be very effective in carefully selected patients and the technique is now being adopted in hospitals across the UK. The aim of this study is to collect data from people undergoing these procedures at hospitals across the UK to find out how well they work in practice and what factors influence response.

Who can participate?
Patients aged over 18 with emphysema undergoing a lung volume reduction procedure

What does the study involve?
The study involves collecting routine data about lung volume reduction procedures onto a central database. Results from across the UK can then be used to improve understanding of the procedures. Participants are not required to do anything in addition. Data is collected at the start of the study and at 3-month and 12-month follow up, including lung function data, measures of exercise capacity (maximum amount of exercise that a patient can sustain), questionnaires about health status and CT scan results.

What are the possible benefits and risks of participating?
This study will make it easier to assess lung volume reduction procedures and bring new treatments into play more quickly. There are no risks to participants.

Where is the study run from?
1. Royal Brompton Hospital (UK)
2. Glenfield Hospital (UK)
3. Addenbrooke's Hospital (UK)
4. Oxford Health NHS Foundation Trust (UK)
5. University Hospitals Bristol NHS Foundation Trust (UK)
6. Liverpool Heart and Chest NHS Foundation Trust (UK)

7. University Hospital of Wales (UK)
8. University Hospital of South Manchester NHS Foundation Trust (UK)
9. Sheffield Teaching Hospitals NHS Foundation Trust (UK)
10. Leeds Teaching Hospitals NHS Trust (UK)
11. The Newcastle on Tyne Hospitals NHS Foundation Trust (UK)
12. The Royal Wolverhampton Hospitals NHS Trust (UK)
13. Heart of England NHS Foundation Trust (UK)

When is the study starting and how long is it expected to run for?
April 2015 to December 2026

Who is funding the study?
British Lung Foundation (UK)

Who is the main contact?
Ms Sara Buttery
s.buttery@rbht.nhs.uk

Contact information

Type(s)
Public

Contact name
Ms Sara Buttery

Contact details
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Additional identifiers

EudraCT/CTIS number

IRAS number
190196

ClinicalTrials.gov number

Secondary identifying numbers
IRAS Project ID: 190196

Study information

Scientific Title

UK Lung Volume Reduction: a multicentre observational study

Acronym
UKLVR

Study objectives
COPD is poorly responsive to medical therapy, but new bronchoscopic treatments for emphysema offer the prospect of significant benefits for patients, improving lung function, exercise capacity and possibly survival. It is important to ensure that benefits seen in clinical trials are in fact reflected in clinical practice. The study will collect data on procedures being performed across the UK to establish whether the clinical effects are similar to those seen in trials and which factors predict the best outcomes.

Ethics approval required
Old ethics approval format

Ethics approval(s)
London – Camberwell St Giles Research Ethics Committee, 21/07/2016, ref: 16/LO/1107

Study design
Multicentre longitudinal observational study

Primary study design
Observational

Secondary study design
Longitudinal study

Study setting(s)
Hospital

Study type(s)
Treatment

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

Health condition(s) or problem(s) studied
Emphysema

Interventions
Lung volume reduction procedures for emphysema include lung volume reduction surgery, endobronchial valve placement, lung volume reduction coils. This study collects data from people undergoing these procedures at hospitals across the UK to evaluate how well they work in practice and what factors at baseline influence response. Baseline, 3-month and 12-month follow-up data are collected. This includes lung function data, measures of exercise capacity, questionnaires about health status and CT scan results.

Intervention Type
Procedure/Surgery

Primary outcome measure
Forced expiratory volume in one second, measured by spirometry at baseline and 3 months post procedure

Secondary outcome measures
1. Walking distance, measured by 6 minute walk test or incremental shuttle walk test, at baseline, 3 and 12 months
2. Health status, measured by COPD assessment test (CAT) score or SGRQ at baseline, 3 and 12 months
3. Residual volume, measured by body plethysmography at baseline, 3 and 12 months

Overall study start date
01/04/2015

Completion date
01/12/2026

Eligibility

Key inclusion criteria
Patients aged over 18 with emphysema undergoing a lung volume reduction procedure

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
300

Key exclusion criteria
Not meeting the inclusion criteria

Date of first enrolment
01/12/2016

Date of final enrolment
31/03/2026

Locations

Countries of recruitment

England

United Kingdom

Wales

Study participating centre
Royal Brompton Hospital
Fulham Rd
London
United Kingdom
SW3 6NP

Study participating centre
Glenfield Hospital
Groby Rd
Leicester
United Kingdom
LE5 4QF

Study participating centre
Addenbrooke's Hospital
Hills Rd
Cambridge
United Kingdom
CB2 0QQ

Study participating centre
Oxford Health NHS Foundation Trust
John Smith Dr
Oxford
United Kingdom
OX4 2GX

Study participating centre
University Hospitals Bristol NHS Foundation Trust
Marlborough Street
Bristol
United Kingdom
BS1 3NU

Study participating centre
Liverpool Heart and Chest NHS Foundation Trust
Thomas Dr
Liverpool
United Kingdom
L14 3PE

Study participating centre
University Hospital of Wales
Heath Park
Cardiff
United Kingdom
CF14 4XW

Study participating centre
University Hospital of South Manchester NHS Foundation Trust
Southmoor Rd
Manchester
United Kingdom
M23 9LT

Study participating centre
Sheffield Teaching Hospitals NHS Foundation Trust
Herries Rd
United Kingdom
S5 7AU

Study participating centre
Leeds Teaching Hospitals NHS Trust
Beckett Street
Leeds
United Kingdom
LS9 7TF

Study participating centre
The Newcastle on Tyne Hospitals NHS Foundation Trust
Freeman Road
Newcastle on Tyne
United Kingdom
NE7 7DN

Study participating centre
The Royal Wolverhampton Hospitals NHS Trust
Wolverhampton Rd
Wolverhampton
United Kingdom
WV10 0QP

Study participating centre
Heart of England NHS Foundation Trust
Bordesley Green East
Birmingham
United Kingdom
B9 5ST

Sponsor information

Organisation
Imperial College London

Sponsor details
Faculty of Medicine Centre
Room 5L10B, Lab Block
London
England
United Kingdom
W6 8RF

Sponsor type
University/education

ROR
https://ror.org/041kmwe10

Funder(s)

Funder type
Charity

Funder Name

British Lung Foundation

Alternative Name(s)
BLF

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
United Kingdom

Results and Publications

Publication and dissemination plan
To be confirmed at a later date

Intention to publish date
01/12/2027

Individual participant data (IPD) sharing plan
Participant data is held in a secure database. This includes procedures performed, lung function exercise capacity and health status measures. Researchers can apply to the trial steering committee if they have research questions that they wish to address.

IPD sharing plan summary
Stored in repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No