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CELEB: Lung volume reduction in COPD - surgery

Submission date 23/05/2016	**Recruitment status** No longer recruiting	[X] Prospectively registered [X] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 23/05/2016	**Overall study status** Completed	
Last Edited 03/05/2023	**Condition category** Respiratory	

Plain English summary of protocol

Background and study aims
Chronic obstructive pulmonary disease (COPD) is the collective name for a group of diseases which affect the lungs. One of the diseases is emphysema, a lung condition in which the tiny air sacs (alveoli) in the lungs become damaged over time. In emphysema, the alveoli become overfilled with air, causing the walls to weaken and eventually burst, creating one larger air space instead of many small ones. This means that the sufferer is unable to breathe out fully, leading to breathlessness which becomes progressively worse. Lung volume reduction surgery (LVRS) is an operation in which the worst affected part of the lung is removed, making more space for the remaining healthier lung to function. There is good evidence that in properly selected individuals this can improve breathlessness and increase life expectancy. It is a major operation and does carry a risk of complications however. A more recent approach is to use a fibreoptic camera (bronchoscope) to place valves into the airways of the lung. These stop air from entering the worst-affected section of the lung causing it to collapse, leading to similar benefits of LVRS. The aim of this study is to compare the effectiveness of these two techniques in the treatment of patients with emphysema.

Who can participate?
Adults with a heterogeneous pattern of emphysema (isolated to certain areas of the lungs and to a varying extent between segments of the lungs)

What does the study involve?
Participants are randomly allocated to one of two groups. Those in the first group undergo lung volume reduction surgery. Those in the second group have endobronchial valves placed into their airways using a bronchoscope while they are sedated. One year after the procedures, participants in both groups undergo a number of physical tests to find out if their lung function has improved as well as their overall quality of life.

What are the possible benefits and risks of participating?
Not provided at time of registration

Where is the study run from?
1. Royal Brompton Hospital (UK)
2. Glenfield Hospital (UK)
3. St Bartholomew's Hospital (UK)

4. Northern General Hospital (UK)
5. Golden Jubilee National Hospital (UK)

When is the study starting and how long is it expected to run for?
April 2016 to September 2020

Who is funding the study?
National Institute for Health Research (UK)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
30523

Study information

Scientific Title
The CELEB trial: Comparative Effectiveness of Lung volume reduction surgery for Emphysema and

Acronym
CELEB

Study objectives

The aim of this study is to evaluate the relative effectiveness and value of two options currently available for the treatment of COPD patients with a heterogeneous pattern of emphysema. These are lung volume reduction surgery (LVRS) and the bronchoscopic placement of endobronchial valves (BLVR).

Ethics approval required
Old ethics approval format

Ethics approval(s)
London - Fulham Research Ethics Committee, 18/02/2016, ref: 16/LO/0286

Study design
Interventional; Design type: Treatment, Device, Surgery

Primary study design
Interventional

Secondary study design
Randomised parallel trial

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
Patients will be randomised to either unilateral video assisted thoracoscopic (VATS) lung volume reduction surgery (LVRS) or endobronchial valves (BLVR) placed to achieve lobar occlusion.

Intervention Type
Device

Primary outcome measure
Change in iBODE score (a composite of BMI, FEV1, MRC dyspnoea score and shuttle walk test distance) one year post procedure.

Secondary outcome measures
1. Health related quality of life is measured using the COPD assessment test score (CAT)
2. Physical activity level
3. Change in residual volume (RV)
4. Fat free mass

Overall study start date

01/04/2016

Completion date
30/09/2020

Eligibility

Key inclusion criteria
1. Adults (aged 18 or over) with COPD
2. FEV1 <60% predicted
3. Significant hyperinflation (TLC>100% predicted, RV>170% predicted)
4. Ex-smoker >3 months
5. MRC dyspnoea score 3 or more
6.
CT scan assessed at MDT to have intact interlobar fissures (>90%) and heterogeneous emphysema

7. Provision of informed consent to participate

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 76; UK Sample Size: 76

Total final enrolment
88

Key exclusion criteria
1. Smoking within 3 months
2. CT scan shows interlobar fissures are not intact
3. Major comorbidity limiting survival
4. Significant pulmonary fibrosis
5. FEV1 and TLco <20%
6. PaO2 < 7.0kPa
7. PaO2 > 7kPa
8. Presence of interlobar collateral ventilation assessed by Chartis system

Date of first enrolment
01/06/2016

Date of final enrolment

01/06/2019

Locations

Countries of recruitment
England

Scotland

United Kingdom

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

Study participating centre
Glenfield Hospital
University Hospitals Leicester
United Kingdom
LE3 9QP

Study participating centre
St Bartholomew's Hospital
Barts Health NHS Foundation Trust
United Kingdom
EC1A 7BE

Study participating centre
Northern General Hospital
Sheffield
United Kingdom
S5 7AU

Study participating centre
Golden Jubilee National Hospital
Glasgow
United Kingdom
G81 4DY

Sponsor information

Organisation
Royal Brompton and Harefield NHS Foundation Trust

Sponsor details
Fulham Road
London
England
United Kingdom
SW3 6NP

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/02218z997

Funder(s)

Funder type
Government

Funder Name
National Institute for Health 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

Publication and dissemination plan
Not provided at time of registration

Intention to publish date
30/09/2021

Individual participant data (IPD) sharing plan
Not provided at time of registration

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	17/10/2018	30/10/2019	Yes	No
Results article		27/04/2023	03/05/2023	Yes	No
HRA research summary			28/06/2023	No	No