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Exploring the effects of identifying abnormal air flow between lung areas in patients with COPD, using hyperpolarised xenon MRI

Submission date 31/07/2025	**Recruitment status** Recruiting	[X] Prospectively registered [X] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [X] Record updated in last year
Registration date 26/08/2025	**Overall study status** Ongoing	
Last Edited 26/08/2025	**Condition category** Respiratory	

Plain English summary of protocol

Background and study aims
Endobronchial valves (EBV) can help patients with COPD by deflating damaged areas of the lung and improving their breathing. EBVs don't always work if there is hidden air flow around the lung areas (known as collateral ventilation). This study will test whether a new scanning technique using MRI and xenon gas (HPX-MRI) can detect this and help identify who EBV will work for.

Who can participate?
Any patient diagnosed with COPD, aged 18 or above, who is being considered for EBV treatment to help with their symptoms. They may have been planned for treatment and have agreed to undergo treatment, or they may have been reviewed and deemed ineligible for the treatment.

What does the study involve?
i. Two research visits at Oxford University Hospitals NHS Foundation Trust (before and after the treatment, over 6 months)
ii. Following consent, at each visit, the participant will:
1. Fill in questionnaires about their medical history and symptoms
2. Have an MRI scan, which will include breathing in xenon gas
3. Participants may be asked to repeat their lung function test or CT scan already being done as part of assessing their suitability for EBV
iii. Information will be used from the participant and their medical records, but only what's needed for the research study.

What are the possible benefits and risks of participating?
There are no direct benefits from participating in this study, but the contribution through participation could improve EBV treatment for others in the future. The study may involve the following risks:
i. MRI is safe but not suitable for some people with pacemakers or metal implants.

ii. Xenon gas is safe but may briefly make the participant's voice sound deeper or the participant may feel lightheaded for less than a minute.
iii. The participant may need an extra CT scan, which uses a small amount of radiation.

Where is the study run from?
The Oxford University Hospitals NHS Foundation Trust, UK

When is the study starting and how long is it expected to run for?
January 2025 to December 2027

Who is funding the study?
The Medical Research Council (MRC), UK

Who is the main contact?
Prof Fergus Gleeson, Fergus.Gleeson@ouh.nhs.uk

Contact information

Type(s)
Principal Investigator

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
346681

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
CPMS 63653

Study information

Scientific Title
HypErpolarised Xenon PuLmonary MRI in the evaluation for endobronChial lung volume reductIon Therapy (EXPLICIT)

Acronym
EXPLICIT

Study objectives
- Primary Objective: To characterise the pattern of ventilation on hyperpolarised xenon-129 MRI (HPX-MRI) in those with confirmed collateral ventilation (CV) and those treated with endobronchial valve (EBV) insertion for lung volume reduction therapy (LVRT)

- Secondary Objective: To describe the physiological changes of the lungs seen on HPX-MRI post-EBV treatment

Ethics approval required
Ethics approval required

Ethics approval(s)

Approved 07/07/2025, West of Scotland REC 3 (1055 Great Western Road, Glasgow, G12 0XH, United Kingdom; +44 (0)141 314 0211; ggc.WoSREC3@nhs.scot), ref: 25/WS/0116

Study design
Non-randomized feasibility/pilot study

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Hospital, Medical and other records

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
Ventilation in endobronchial valve (EBV) insertion for lung volume reduction therapy (LVRT)

Interventions
This study will be conducted over 24 months, comprising two patient cohorts - Cohort A, COPD patients selected and planned for endobronchial valve (EBV) treatment and Cohort B, COPD patients deemed ineligible for EBV treatment following their workup, i.e. deemed unsuitable for EBV treatment.

The study will recruit patients via the local hospital-based tertiary COPD clinics. Participants who have been worked up for EBV therapy and their cases discussed at the local COPD multi-disciplinary team (MDT) meeting will be identified by a clinician and informed of the study. COPD MDT comprises respiratory physician(s), thoracic surgeon(s), thoracic radiologist(s), specialist nurse(s), respiratory physiotherapist(s) and/or occupational therapist(s). If patients agree to be contacted, a member of the research team will contact them, explain the study, and assess eligibility.

The routine clinical data for work-up for EBV therapy is a thin-section volumetric CT chest (and quantitative CT analysis using Stratx software)+/- Chartis assessment, full pulmonary function tests (PFTs), 6-minute walk test (6MWT), COPD assessment test (CAT) and St. George's Respiratory Questionnaire (SGRQ). The study will record the data obtained from these clinical assessments as part of the research study.

The additional investigations that will be added to this are an HPX-MRI chest scan as a baseline scan and a follow-up HPX-MRI and CT chest (if not performed as part of clinical care or recent acute events believed to have possibly altered the lung tissues) scans. These follow-up scans will be 6 months (+-2 weeks) after their EBV treatment for Cohort A and 6 months after their

baseline visit for Cohort B. All the assessments carried out in the baseline visit will be repeated unless repeat PFTs, chest CT and 6MWT have been performed as part of their clinical follow-up for Cohort A. The HPX-MRI scans will not be used in the patient's clinical care.

In summary, the additional tests for the research participants are two HPX-MRI scans and one to two CT chest scans (with 1 litre bag of air, inspiration only). The additional radiation risk from the CT chest scan(s) will be adequately explained to the research participants verbally and in the study participants' information sheets (PIS). The research team will endeavour to organise these additional tests to be done on the same day as any planned clinical appointments. Otherwise, the research team will invite the participants to complete these additional research assessments for one additional research visit at baseline and one additional research visit at follow-up.

All information will be stored in a trial-specific database on our locally approved, secure, on-site Radiology Research server.

Intervention Type
Procedure/Surgery

Primary outcome measure
Differences in the pattern of ventilation measured using on hyperpolarised xenon-129 MRI (HPX-MRI) in those with confirmed collateral ventilation (CV) and those treated with EBV at baseline and follow-up (6 months)

Secondary outcome measures
Quantitative and/or qualitative differences of HPX-MRI findings at baseline and follow-up (6 months)

Overall study start date
01/01/2025

Completion date
31/12/2027

Eligibility

Key inclusion criteria
1. Aged 18 years or over
2. Willing and able to give informed consent
3. Worked up for EBV therapy in the local COPD clinic

Cohort A – No evidence of CV and eligible for EBV treatment
MDT and patient decision for EBV therapy

Cohort B – Ineligible for EBV treatment following current standard assessments
MDT decision not for EBV therapy

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 40; UK Sample Size: 40

Key exclusion criteria
1. Pregnant, lactating or planning pregnancy during the study
2. Inability to lie flat for imaging
3. Contraindications to MRI examinations as locally determined
4. Any other reason, as determined by the study investigators, that renders the participant ineligible for the study

Date of first enrolment
26/08/2025

Date of final enrolment
26/02/2027

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
John Radcliffe Hospital
Headley Way
Headington
Oxford
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OX3 9DU

Sponsor information

Organisation
Oxford University Hospitals NHS Trust

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Sponsor type
Hospital/treatment centre

Website
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ROR
https://ror.org/03h2bh287

Funder(s)

Funder type
Government

Funder Name
Medical Research Council

Alternative Name(s)
Medical Research Council (United Kingdom), UK Medical Research Council, MRC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Planned publication in a peer-reviewed journal

Intention to publish date
31/12/2028

Individual participant data (IPD) sharing plan

The datasets generated and/or analysed during the current study will be published as a supplement to the results publication

IPD sharing plan summary

Published as a supplement to the results publication

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file	version 1.0	01/07/2025	26/08/2025	No	No