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Identifying and investigating abnormal areas on the lung using UV light

Submission date 28/01/2020	**Recruitment status** Suspended	[_] Prospectively registered [X] Protocol
Registration date 12/03/2020	**Overall study status** Ongoing	[_] Statistical analysis plan [_] Results
Last Edited 08/08/2022	**Condition category** Respiratory	[_] Individual participant data [_] Record updated in last year

Plain English summary of protocol

Background and study aims

Pneumothorax is air in the chest which causes the lung to collapse. This can occur spontaneously without any other injury to the chest. Primary spontaneous pneumothorax (PSP) usually refers to young patients without known lung disease, who were traditionally thought to have normal lungs. This view is now being challenged, but the true reason for their lung to leak air (and hence collapse) is not known.

This study will use a new technique to show up abnormal areas in the lung by asking patients to inhale a drug called fluorescein. Fluorescein glows bright green under ultraviolet (UV) light. Therefore, when a patient has surgery to prevent another collapsed lung, we can use UV light to show where the fluorescein is coming abnormally close to the lung surface.

We think these areas are the source of the air leak and will therefore have a different structure with some chemicals being over- (or under-) produced. The lung structure (histology) will be looked at under the microscope and the chemicals being produced (mRNA) will be analysed. Importantly, we will be comparing areas that look normal and abnormal in the same patient and also with other patients who have not had a pneumothorax (the control group).

Who can participate?

Patients aged 16 – 55 years, either undergoing Video-assisted Thoracoscopic Surgery (VATS) or thoracic surgery.

What does the study involve?

During surgery patients will be asked to breathe in Fluorescein to show up any abnormal areas on the lung surface.

The surgery will not be any difference to usual, but within the part of the lung removed, 2 or 3 areas will be used for analysis. Patients will also be asked to perform some extra breathing tests (lung function), if time allows, before your surgery, and to provide a blood sample (5ml).

What are the possible benefits and risks of participating?

The study is not designed to change this participants treatment, but an increased understanding of the causes of pneumothorax may benefit patients in the future.

The procedure is very safe and the surgery will not take longer than usual. The lung tissue that used for analysis is tissue that would have been removed anyway. Fluorescein has been used in this way before with no reported side effects, except for a slight yellow discolouration of the mouth, which goes away after 1-2 days. The laser system used for measuring the levels of oxygen and carbon dioxide uses a low power system and the light is entirely enclosed within the device and is therefore harmless.

Where is the study run from?
Oxford Centre for Respiratory Medicine (UK)

When is the study starting and how long is it expected to run for?
March 2020 to March 2026

Who is funding the study?
1. Oxfordshire Health Services Research Committee (UK)
2. Medical Sciences Division Research Fund (University of Oxford) (UK)

Who is the main contact?
Dr Rob Hallifax
Robert.Hallifax@ndm.ox.ac.uk

Contact information

Type(s)
Scientific

Contact name
Dr Rob Hallifax

ORCID ID
http://orcid.org/0000-0002-9467-668X

Contact details
Oxford Centre for Respiratory Medicine
Churchill Hospital
Old Road
Oxford
United Kingdom
OX3 7LE
+44 (0)7989966210
Robert.Hallifax@ndm.ox.ac.uk

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
263552

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
IRAS 263552

Study information

Scientific Title
Primary pneumothorax fluorescein-enhanced thoracoscopy

Acronym
PREFECT

Study objectives
The underlying cause of primary spontaneous pneumothorax is not known. We hypothesize that abnormal areas can be highlighted by use of inhaled fluorescein at thoracic surgery, and the abnormalities can be quantified by a combination of histological analysis of subpleural architecture and mRNA expression.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 17/09/2019, East of England - Cambridgeshire and Hertfordshire Research Ethics Committee
(The Old Chapel, Royal Standard Place, Nottingham, NG1 6FS; +44 (0)207 104 8106; nrescommittee.eastofengland-cambsandherts@nhs.net), ref: 19/EE/0235

Study design
Exploratory study

Primary study design
Other

Secondary study design

Study setting(s)
Hospital

Study type(s)
Diagnostic

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
Primary spontaneous pneumothorax

Interventions
Administration of inhaled fluorescein at Thoracic Surgery to highlight areas of lung abnormalities.

During surgery patients will be asked to breathe in Fluorescein to show up any abnormal areas on the lung surface.
The surgery will not be any different to usual, but within the part of the lung removed, 2 or 3 areas will be used for analysis. Patients will also be asked to perform some extra breathing tests (lung function), if time allows, before your surgery, and to provide a blood sample (5ml).
The samples will be looked at under the microscopy (histology) and by mRNA analysis.
No additional patient follow-up is required.

Intervention Type
Procedure/Surgery

Primary outcome measure
Descriptive histological findings in lung areas under investigation, measured by the researchers

Secondary outcome measures
1. Lung genomic analysis measured using mRNA sequencing
2. Autofluorescence measured using digital image analysis software
3. Degree of lung inhomogeneity measured using laser gas analyser (bespoke project with University of Oxford Department of Physiology)
4. Peripheral blood genomic analysis measured using mRNA sequencing

Overall study start date
01/06/2019

Completion date
01/03/2026

Eligibility

Key inclusion criteria
1. Patient undergoing Video-assisted Thoracoscopic Surgery (VATS) for pneumothorax recurrence prevention, or ongoing air leak (pneumothorax group) OR Thoracic surgery for another indication, for example, early-stage lung cancer or metastasis resection (control group).
2. Male or female aged between 16 and 55 years (inclusive)

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
28

Key exclusion criteria
1. Inability to consent or comply with the trial requirements
2. Patients in the control group should not have demonstrable emphysema (on CT scanning) and should not have experienced a spontaneous pneumothorax in the past
3. Allergy to fluorescein
4. Any other significant disease or disorder which, in the opinion of the Investigator, may either put the participants at risk because of participation in the study, or may influence the result of the trial, or the participant's ability to participate in the study

Date of first enrolment
01/03/2020

Date of final enrolment
01/09/2025

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Oxford Centre for Respiratory Medicine
Churchill Hospital
Old Road
Oxford
United Kingdom
OX3 7LE

Sponsor information

Organisation
University of Oxford

Sponsor details
Clinical Trials and Research Governance
Joint Research Office, Block 60
Churchill Hospital
Old Road
Oxford
England
United Kingdom

OX3 7LE
+44 (0)1865 572228
ctrg@admin.ox.ac.uk

Sponsor type
University/education

Website
http://www.ox.ac.uk/

ROR
https://ror.org/052gg0110

Funder(s)

Funder type
Government

Funder Name
Oxfordshire Health Services Research Committee Grant (Ref 1314)

Funder Name
Medical Sciences Division Research Fund (University of Oxford)

Results and Publications

Publication and dissemination plan
The preparation of a manuscript for rapid publication in a peer reviewed journal will be a priority for and responsibility of the Chief Investigator. The Study Management Group will also take responsibility for reviewing drafts of any manuscripts, abstracts, press releases and other publications arising from this study.

Intention to publish date
01/09/2026

Individual participant data (IPD) sharing plan
All data generated or analysed during this study will be included in the subsequent results publication.

IPD sharing plan summary
Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file	version V1.0	18/06/2019	12/03/2020	No	No
HRA research summary			28/06/2023	No	No