

Identifying and investigating abnormal areas on the lung using UV light

Submission date 28/01/2020	Recruitment status Suspended	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 12/03/2020	Overall study status Ongoing	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 08/08/2022	Condition category Respiratory	<input type="checkbox"/> Individual participant data <input type="checkbox"/> 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?
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Contact information

Type(s)
Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
263552

ClinicalTrials.gov (NCT)

Nil known

Protocol serial number

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

Study type(s)

Diagnostic

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(s)

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

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Adult

Sex

All

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

United Kingdom

England

Study participating centre

Oxford Centre for Respiratory Medicine

Churchill Hospital

Old Road

Oxford

United Kingdom

OX3 7LE

Sponsor information

Organisation

University of Oxford

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

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?
HRA research summary			28/06/2023	No	No
Protocol file	version V1.0	18/06/2019	12/03/2020	No	No