ISRCTN63607895 https://doi.org/10.1186/ISRCTN63607895

Protocol for lung sample collection by bronchoscopy for laboratory research

Submission date
24/03/2026

Recruitment status
Recruiting

Registration date
24/03/2026

Overall study status
Ongoing

Last Edited
24/03/2026

Condition category
Respiratory

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
This study aims to obtain samples from the lungs and blood samples from healthy participants and participants with chronic obstructive pulmonary disease (COPD), asthma and interstitial lung disease (ILD) for laboratory research relating to the causes and treatment of disease in order to identify markers of disease and drug effect or development of new laboratory methods.

Who can participate?
Men and women aged 18 years or over who are healthy or who have COPD, asthma, or ILD

What does the study involve?
This study will involve at least two visits to the Medicines Evaluation Unit. After written informed consent is obtained, participants will be assessed for their eligibility to have a bronchoscopy to collect the samples by undergoing the following tests: spirometry (breathing test), DLCO (breathing test; ILD participants only), physical examination, oxygen saturations via a finger clip, and blood sampling for routine safety. We may need to repeat some tests at a separate visit. Suitable participants may undergo bronchoscopy at a separate visit. During the bronchoscopy visit, a small tube is put in your vein (cannula) to take some blood and give sedative medication. The doctor will also use local anaesthetic on your nose and throat. A small flexible camera (bronchoscope) will be passed into your lungs through your nose or mouth. The following samples may be collected: a biopsy (small piece of lung tissue), a brush (a small brush which is rotated to collect lung cells), a lavage/wash (saline is put into your lung and gently sucked back out), and bronchosorption (a small strip will soak up some of the lining fluid from your lungs). Your heart rate, blood pressure and oxygen levels will be monitored. Some participants may be asked to attend an additional visit for nasal biopsy. This is a small piece of tissue collected from your nasal passage after the doctor has given you local anaesthetic. We may also collect a brush (a small brush which is rotated to collect nasal cells) or a wash (saline is put into your nose and gently sucked back out).

What are the possible benefits and risks of participating?
The bronchoscopy will only take place if the doctor considers it safe to do so. Minor effects such as a sore nose and throat are common after bronchoscopy.
If you have a biopsy taken, you may also notice that your sputum is blood streaked for a few

hours after the procedure. This is caused by tiny bleeding from the biopsy sites. This is normal after bronchoscopy and normally settles by itself. If you have a brushing taken, a small nylon brush will be passed through the bronchoscope and the walls of your airways will be gently brushed to obtain small cell samples to be examined. Minor bleeding may occur during this procedure. You may cough up a small amount of blood after the bronchoscopy. If you have a bronchosorption sample taken, a thin plastic wire with synthetic material on the end will be inserted through the bronchoscope into your airways and held there for up to 2 mins against the wall. There have been no major complications from bronchosorption. There could be a potential risk that the synthetic material could come away from the wire, which would require bronchial biopsy forceps to remove it.
Occasionally the saline used to wash out your airways can cause a temporary rise in body temperature. This is called post-bronchoscopy fever and is a recognised occurrence after bronchoscopy. This is not serious and should settle within a day. There is a 6-8% risk of infection and routine protection with antibiotics is not usually recommended. You should contact us if you feel unwell or are worried about anything once you have gone home.
More serious side effects are very rare. Biopsies rarely cause heavier bleeding which needs treatment with adrenaline (this reduces the blood flow). Very rarely, biopsies can result in an air leak from the airways. This will usually settle on its own but if complicated, which is very rare, may need to be treated with a tube (drain) inserted into the side of the chest.
Bronchoscopy could pose a small risk to an unborn child; women who are pregnant or breastfeeding will not be able to take part in the study.
If you have a nasal biopsy, you may feel slight pressure when the nasal biopsy is taken, it should not be painful. A small amount of bleeding is normal after the procedure and usually stops on its own, sometimes we need to apply a solution to the place of biopsy to stop the bleeding. There is a small risk of side effects such as bruising, bleeding and infection from the cannula and/or blood samples. This is laboratory research so there is no direct benefit to the participant.

Where is the study run from?
Medicines Evaluation Unit (UK)

When is the study starting and how long is it expected to run for?
September 2007 to December 2030

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
Natalie Jackson, njackson@meu.org.uk

Contact information

Type(s)
Scientific, Public

Contact name
Miss Natalie Jackson

Contact details
Medicines Evaluation Unit
The Langley Building
Southmoor Road

Manchester
United Kingdom
M23 9QZ
+44 (0)1619464065
njackson@meu.org.uk

Type(s)
Principal investigator

Contact name
Prof Dave Singh

Contact details
Medicines Evaluation Unit
The Langley Building
Southmoor Road
Manchester
United Kingdom
M23 9QZ
+44 (0)1619464073
dsingh@meu.org.uk

Additional identifiers

Integrated Research Application System (IRAS)
197998

Study information

Scientific Title
Bronchoscopy studies in patients with asthma, chronic obstructive pulmonary disease, interstitial lung disease and healthy controls; identification of new therapeutic targets

Study objectives
Identifying markers of disease and developing new assays to identify and validate novel therapeutic targets in patients with asthma, COPD and ILD.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 09/11/2006, South Manchester Research Ethics Committee (now North West – Greater Manchester (GM) South) (3rd Floor, Barlow House 4 Minshull Street, Manchester, M1 3DZ, United Kingdom; +44 (0)207 104 8143; gmsouth.rec@hra.nhs.uk), ref: 06/Q1403/156

Primary study design
Observational

Secondary study design
Cross sectional study

Study type(s)

Health condition(s) or problem(s) studied
Chronic obstructive pulmonary disease (COPD), asthma, interstitial lung disease (ILD)

Interventions
Participants will undergo the following assessments for suitability for bronchoscopy: spirometry, DLCO (ILD patients only), physical examination, oxygen saturations via a pulse oximeter, blood sampling for safety (e.g. Full Blood Count (FBC) and coagulation).

Suitable participants may undergo bronchoscopy. For bronchoscopy, a sedative agent is given via intravenous (IV) cannula. A bronchoscope is passed through the nose or mouth to visualise the airways. Topical anaesthesia is used as required to anaesthetise the nasal passage, vocal cords, trachea and bronchial tree. The following samples may be collected from the lung: Bronchial mucosal biopsies, bronchoalveolar lavage, bronchial brushings and bronchial absorption. A venous blood sample may also be collected for laboratory research.

A subset of participants may attend an additional visit for nasal biopsy. Local anaesthesia will be used. Nasal washings and brushings may also be performed.

Intervention Type
Other

Primary outcome(s)
1. Bronchoalveolar lavage fluid (BALF) cell counts in stable state measured using cytology at a single timepoint

2. BALF cytokines including IL-8 and TNF-α in stable state measured using immunoassay at a single timepoint

Key secondary outcome(s)
1. Bronchial biopsy immunohistochemistry including IL-33 expression in the bronchial epithelium in stable state measured using immunohistochemistry at a single timepoint

Completion date
31/12/2030

Eligibility

Key inclusion criteria
1. Must be aged over 18 years, be competent to understand and give informed consent
2. Participants with asthma, COPD and ILD must have stable disease with no exacerbations or infections for at least 6 weeks prior to bronchoscopy

Participants with asthma must have:
1. Clinically diagnosed asthma
2. Forced Expiratory Volume in 1 Second (FEV1) >30% predicted
3. FEV1 > 1.0 litre; participants with FEV1 >30% predicted but <1 litre may undergo a restricted procedure with only one lung undergoing lavage as judged by the investigator
4. Oxygen saturation above 90% on room air

Participants with COPD must have:
1. Clinically diagnosed COPD
2. FEV1 >30% predicted
3. FEV1 >1.0 L; participants with FEV1 >30% predicted but <1 litre may undergo a restricted procedure with only one lung undergoing lavage as judged by the investigator
4. Smoking history of at least 10 pack years
5. Oxygen saturation above 90% on room air

Participants with ILD must have:
1. Diffusing Capacity for Carbon Monoxide (DLCO) >35% predicted
2. Forced Vital Capacity (FVC) >45% predicted
3. Oxygen saturation above 90% on room air

Healthy participants must have:
1. No history of a chronic respiratory disorder
2. No history of acute respiratory disease within 6 weeks prior to bronchoscopy
3. No other significant medical disorder that may affect the respiratory system or that causes significant disability

Healthy participants who are smokers must:
1. Be current or ex-cigarette smokers with a smoking history of at least 10 pack-years
2. Have FEV1 >90% predicted

Healthy participants who are non-smokers must have:
No significant smoking history as judged by the investigator

Healthy volunteers allowed
Yes

Age group
Mixed

Lower age limit
18 Years

Upper age limit
90 Years

Sex
All

Total final enrolment
0

Key exclusion criteria
All participants:
1. History of any other inflammatory lung condition or carcinoma of the lung
2. Participants who are taking warfarin or have any bleeding disorders
3. Women who are pregnant or breastfeeding

Participants with respiratory conditions:
1. Exacerbation of disease requiring hospitalisation within previous 6 months
2. History of ITU admission secondary to asthma, COPD or ILD
3. Use of home oxygen for COPD or ILD

Date of first enrolment
11/09/2007

Date of final enrolment
31/12/2030

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Medicines Evaluation Unit Limited
The Langley Building
Southmoor Road
Wythenshawe
Manchester
England
M23 9QZ

Sponsor information

Organisation
Medicines Evaluation Unit

ROR
https://ror.org/05e497m36

Funder(s)

Funder type

Funder Name
Investigator initiated and funded

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available