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Understanding how COPD flare-ups change the body's recovery process

Submission date
21/03/2025

Recruitment status
Recruiting

Registration date
21/11/2025

Overall study status
Ongoing

Last Edited
12/03/2026

Condition category
Respiratory

[X] 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
Chronic obstructive pulmonary disease (COPD) is the fourth leading cause of death globally, costing the NHS approximately £1.9 billion per year. People with COPD can experience "flare-ups" known as exacerbations. These flare-ups can lead to hospitalisation and increase the likelihood of patients having further readmissions to hospital. This study aims to investigate the effect of an acute flare-up of COPD on the body's ability to resolve inflammation. These flare-ups are associated with an overall worsening of the disease, and currently, there is limited understanding of why patients don't fully recover and how frequent flare-ups lead to a decline in health.

Who can participate?
Adult patients who have been admitted to the hospital due to a flare-up of COPD will be invited to take part in the study.

What does the study involve?
Patients enrolled in the main study will be given the option to donate a spontaneous sputum sample, and the patient's blood sample that was taken on admission to the hospital will also be analysed. Patients enrolled in the main study will be approached to take part in the sub-study, which will involve the donation of a blood sample each day until they are discharged from the hospital. They will also be invited to come back for a 3-month optional follow-up visit.

What are the possible benefits and risks of participating?
There are no direct benefits to the patients taking part in the study. However, the wider COPD population may benefit from the contributions this study's results will have to research in this area. There are minimal risks associated with taking part in this study, and as this is an observational study,

Participation is voluntary and participants can choose to stop at any time without affecting their standard medical care. This study is organised by the University of Leicester, and the findings will help to develop an understanding of the resolution physiology. Results will be published, but personal information will remain confidential and anonymised.

Where is the study run from?
The University of Leicester, UK

When is the study starting and how long is it expected to run for?
March 2026 to November 2027

Who is funding the study?
NIHR Leicester Biomedical Research Centre, UK

Who is the main contact?
Miss Oluwadamilola Yinka-Adebisi, oya3@leicester.ac.uk

Contact information

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Additional identifiers

Integrated Research Application System (IRAS)

355442

Protocol serial number
1072

Study information

Scientific Title
Specialised pro-RESOLVing lipid mediators in the resolution of acute Exacerbations of COPD

Acronym
RESOLVE-COPD

Study objectives
Specialised pro-resolving mediators (SPMs), have the potential to change the course of treatment for those with inflammation, both short-term and long-term. However, the process of how they are produced and each molecules' function are not completely understood. Current treatments for COPD, such as steroids have unwanted side effects including immunosuppression. A more developed understanding can potentially change treatment from being reactive to proactive. This project will help to understand what the levels of different mediators are during an exacerbation, and also how they change as the body works to resolve the inflammation. It may also provide insight into why inflammation is rarely completely resolved in the COPD population and the causes behind patients with frequent exacerbations.

Previous research has investigated the change in SPM levels over time, but not within this population. There have also been studies investigating the different SPM profiles in those with frequent exacerbations vs stable COPD, but they have also concluded that more research is required and stated limitations that are addressed in this research, such as lack of representation in their sample population and the need for sputum samples alongside blood samples to strengthen the analysis.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 11/11/2025, North West - Preston Research Ethics Committee (2 Redman Place, Stratford, London, E20 1JQ, United Kingdom; +44 (0)207 104 8364, 02071048037, 0207 104 8181; preston.rec@hra.nhs.uk), ref: 25/NW/0337

Study design
Single-site cross-sectional study with a longitudinal cohort sub-study

Primary study design
Observational

Study type(s)
Other

Health condition(s) or problem(s) studied
Chronic obstructive pulmonary disease (COPD)

Interventions
This is an observational study. The aim of this study is to investigate the effects of an acute exacerbation of COPD on resolution physiology. This study is divided into a main study and a sub-study. The population is patients admitted to hospital with an acute exacerbation of COPD.

As part of the main study, the surplus of the blood sample taken on admission to hospital will be analysed and participants will be given the option to donate a spontaneous sputum sample.

Participants in the sub-study must already be enrolled in the main study to participate. Participants will donate a blood sample daily from the day of consent until the day they are discharged from the hospital. They will be invited to return for a follow-up visit 3-months post hospitalisation where a 'recovery' sample will be collected.

Intervention Type
Other

Primary outcome(s)
Levels of specialised pro-resolving mediators (SPMs) measured using the Liquid Chromatography Mass Spectrometry (LCMS) in the baseline blood sample

Key secondary outcome(s))
There are no secondary outcome measures

Completion date
01/11/2027

Eligibility

Key inclusion criteria
1. Participant is willing and able to give informed consent for participation in the study
2. Male or Female, aged 18 years old and above
3. Able (in the Investigator's opinion) and willing to comply with all the study requirements
4. Hospitalised following an acute exacerbation

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 years

Upper age limit
100 years

Sex

All

Total final enrolment
0

Key exclusion criteria
1. Female participants who are pregnant or lactating
2. Participant is unwilling or unable to give informed consent for participation
3. Unable (in the Investigators opinion) or unwilling to comply with the study requirements
4. Participants who are unable to understand written and spoken English.
5. Participant has any other significant disease or disorder which, in the opinion of the Investigator may either put the participants at risk, influence their ability to participate in the study or influence the result of the study. This includes but is not limited to - respiratory diseases such as asthma, bronchiectasis, pneumonia and cancer.
6. Patients that require intubation or admission to ICU.

Date of first enrolment
04/03/2026

Date of final enrolment
11/01/2027

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Glenfield General Hospital
Groby Road
Leicester
England
LE3 9QP

Sponsor information

Organisation
University of Leicester

ROR
https://ror.org/04h699437

Funder(s)

Funder type
University/education

Funder Name
NIHR Leicester Biomedical Research Centre

Alternative Name(s)
Leicester Biomedical Research Centre, NIHR Leicester BRC, Leicester BRC

Funding Body Type
Government organisation

Funding Body Subtype
Research institutes and centers

Location
United Kingdom

Results and Publications

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