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Assessing airway twitchiness in patients with severe asthma on biologics as they reduce their inhaled corticosteriod dose

Submission date
15/07/2025

Recruitment status
Recruiting

Registration date
16/07/2025

Overall study status
Ongoing

Last Edited
23/10/2025

Condition category
Respiratory

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

Plain English summary of protocol

Background and study aims
Asthma is a common lung condition that makes breathing difficult, especially when the airways become sensitive or "twitchy" in response to things like dust or pollen. This twitchiness is linked to a type of inflammation in the lungs called type 2 inflammation. People with this kind of asthma often have higher levels of certain markers in their blood and breath.

Asthma is usually treated with inhalers that contain steroids, but these don’t always reach the smallest parts of the lungs. Newer treatments called biologics, which are given by injection, can reach these areas and may help reduce inflammation more effectively.

This study aims to find out whether two commonly used biologic medications, dupilumab and tezepelumab, can reduce airway twitchiness enough that patients can safely lower their dose of steroid inhalers without losing control of their asthma.

Who can participate?
The study is for adults with severe asthma who are already being treated with either dupilumab or tezepelumab.

What does the study involve?
Participants will use a standard steroid inhaler in a specific way called maintenance and reliever therapy. They will attend three study visits over six months, including a screening visit. They will provide blood samples to measure inflammation markers and take breathing tests to check lung function, including a special test to measure how twitchy the airways are.

What are the possible benefits and risks of participating?
Benefits may include better understanding and management of asthma, and possibly reducing the steroid dose safely. Risks include side effects from reducing steroid use, such as worsening asthma symptoms. There are also known side effects from long-term use of high-dose steroid inhalers, which this study hopes to help reduce. Blood tests and breathing tests may cause minor discomfort.

Where is the study run from?
The study is being run at the Scottish Centre of Respiratory Medicine, based at the University of Dundee's Ninewells campus (UK)

When is the study starting and how long is it expected to run for?
May 2024 to August 2026

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
Professor Brian Lipworth, b.j.lipworth@dundee.ac.uk

Contact information

Type(s)
Principal investigator

Contact name
Prof Brian Lipworth

ORCID ID
https://orcid.org/0000-0002-8140-2014

Contact details
Scottish Centre for Respiratory Research Mailbox 2
Molecular & Clinical Medicine School of Medicine
University of Dundee Ninewells Hospital
Dundee
United Kingdom
DD1 9SY
+44 1382383188
b.j.lipworth@dundee.ac.uk

Type(s)
Public, Scientific

Contact name
Dr Robert Greig

ORCID ID
https://orcid.org/0000-0001-7668-286X

Contact details
Scottish Centre for Respiratory Research Mailbox 2
Molecular & Clinical Medicine School of Medicine
University of Dundee Ninewells Hospital
Dundee
United Kingdom
DD1 9SY

+44 1382383188
rgreig001@dundee.ac.uk

Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
346249

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
2-071-24

Study information

Scientific Title
Tailoring Inhaled Corticosteroids in patients with Severe Asthma taking Biologics

Acronym
TICSAB

Study objectives
1. To characterize the effect of tapering inhaled corticosteroids on mannitol airway hyperresponsiveness in patients with severe asthma taking dupilumab or Tezepelumab
2. Assess the effects of taking dupilumab or tezepelumab on small airways dysfunction using airways oscillometry.
3. To characterise symptom control and quality of life scores as participants adjust their inhaled corticosteroid dose.
4. To assess type 2 inflammation in as participants adjust their inhaled corticosteroid dose.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 08/07/2025, East of Scotland Research Ethics Service (EoSRES) (Tayside Medical Science Centre, Residency Block Level 3, George Pirie Way, Ninewells Hospital and Medical School, Dundee, DD1 9SY, United Kingdom; +44 1382660111; tay.eosres@nhs.scot), ref: 25/ES/0043

Study design
Phase IV single arm open labelled

Primary study design
Interventional

Study type(s)

Quality of life, Treatment

Health condition(s) or problem(s) studied
Severe asthma patient on either dupilumab or tezepelumab

Interventions
Participants will already be established on asthma biologic medications (either dupilumab or tezepelumab). Will will be on maximal maintenance and reliever inhaled therapy (Fostair NEXTHaler 100/6 4 puffs BD) and reduce their MART dose as able during the study (between 2 and 8 puffs daily) over a 6 month period. They will undergo airway oscillometry, spirometry, mannitol challenge, blood tests, FeNO and questionnaires to assess symptom control and quality of life at 3 visits (including a screening visit).

Intervention Type
Other

Primary outcome(s)
Mannitol airway hyperresponsiveness measured using change in mannitol PD10 from Visit 1 (post-run-in baseline) to Visit 2 (6 months)

Key secondary outcome(s))
1. Blood eosinophil count is measured using automated haematology analyser at post-run-in baseline and 6 months
2. Total serum IgE is measured using immunoassay (e.g. ImmunoCAP) at post-run-in baseline and 6 months
3. Fractional exhaled nitric oxide (FeNO) is measured using a FeNO analyser (e.g. NIOX VERO) at post-run-in baseline and 6 months
4. Forced expiratory volume in 1 second (FEV1), forced expiratory flow at 25–75% of FVC (FEF25–75), and forced vital capacity (FVC) are measured using spirometry at post-run-in baseline and 6 months
5. Airway resistance (R5–R20) and reactance area (AX) are measured using impulse oscillometry at post-run-in baseline and 6 months
6. Airway hyperresponsiveness is measured using mannitol challenge test with PD15 as the outcome at 6 months
7. Airway reactance area (AX) is measured using impulse oscillometry at post-run-in baseline and 6 months

Completion date
01/08/2026

Eligibility

Key inclusion criteria
1. Any patient over 18 years of age with severe asthma taking dupilumab or tezepelumab for severe asthma for at least 6 months
2. FEV1 ≥50% at baseline

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Upper age limit
100 years

Sex
All

Total final enrolment
46

Key exclusion criteria
1. Any patients on maintenance oral steroids or required an oral steroid burst in the past 28 days
2. Any patient who was switched from another biologic in the past 3 months
3. Any other respiratory condition such as moderate to severe bronchiectasis or COPD
4. Currently pregnant

Date of first enrolment
17/11/2025

Date of final enrolment
10/01/2026

Locations

Countries of recruitment
United Kingdom

Scotland

Study participating centre
Ninewells Hospital and University of Dundee Medical school
Ninewells Avenue
Dundee
United Kingdom
DD1 9SY

Sponsor information

Organisation
TASC - University of Dundee/NHS Tayside

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be available on request from Prof Brian Lipworth (b.j.lipworth@dundee.ac.uk)

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	version 3	30/06/2025	16/07/2025	No	Yes
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Protocol file	version 2	30/06/2025	16/07/2025	No	No