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Biomarkers of asthma remission after dupilumab treatment

Submission date 09/05/2023	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [X] Record updated in last year
Registration date 12/05/2023	**Overall study status** Ongoing	
Last Edited 12/05/2025	**Condition category** Respiratory	

Plain English summary of protocol

Background and study aims
Asthma affects over 350 million people in the world. Approximately 5-10% of people with asthma have severe disease. Asthma is a lung disease associated with inflammation (swelling) of the airways. Certain proteins made by the body, called interleukins, can make this inflammation worse. One of these interleukin proteins is called interleukin- 4Rα (IL4Rα). Interleukin-4Rα appears to play an important role in asthma. It plays a role by helping white blood cells (called eosinophils) stay alive. Eosinophils are involved in the inflammation of the airways. Dupilumab is a medicine that blocks the effect of Interleukin-4Rα on eosinophils (and therefore reduces inflammation). It is given as an injection under the skin and may help reduce inflammation in the airways of people with asthma. Previous research studies in people with severe asthma have shown an improvement in asthma control in those who received dupilumab, and it is now approved for the treatment of severe asthma in the UK. Research studies have shown that people who received dupilumab experienced about half as many asthma exacerbations (severe episodes of asthma or attacks) as those given placebo (dummy) injections. In addition, it also improved their lung function and asthma control. This research study will observe all participants having dupilumab injections as part of their normal clinical care. This will help to understand what might be causing the high levels of disease control, including the absence of symptoms and exacerbations. By doing this, it is hoped that information will be obtained to help improve asthma treatment in the future. The study team will investigate the effect of dupilumab on all aspects of asthma such as changes in quality of life, symptoms, inflammation and breathing tests.

Who can participate?
Adults (≥18 years old) following a clinical decision to initiate dupilumab for severe asthma after meeting licensing, local and national guidelines.

What does the study involve?
Every participant taking part in the study will be receiving dupilumab injections as part of their normal clinical care. Participants will be asked to attend a total of 5 scheduled visits at the study centre. Visit 0 and Visit 1 can be combined where feasible to do so. In between study visits, participants will be asked to complete some breathing tests at home. They will be asked to monitor their peak flow (maximum rate a person can breathe out) and a test for exhaled nitric

oxide (FeNO) every day for the first 4 weeks of the study and then once a week afterwards. This is to monitor the usual variation in their asthma symptoms and airway function, and how this might change if they become unwell.

What are the possible benefits and risks of participating?
There is no guarantee that participants will receive any benefit from this study, and taking part in this study may or may not improve their asthma. Information from this study may help asthma treatment in the future. There are possible risks, disadvantages and inconveniences with any research study. The individual risks of each procedure and investigation are described fully in the participant information sheet. Participants will potentially have more tests and procedures if they take part in the study, compared to standard hospital visits. Study visits could take more time than standard hospital visits and you will have more blood taken. Each study visit can last approximately 1-3 hours. Participants will have to do additional monitoring of their asthma at home as the study requires them to keep track of their peak flow reading and lung inflammation with FeNO (approximately 10 minutes).

Where is the study run from?
This is a research project organised by the NIHR Leicester Biomedical Research Centre – Respiratory, at Glenfield Hospital. This study is part of a larger programme of studies, called 3TR. 3TR is a European research group aimed at improving the treatment of asthma and chronic obstructive pulmonary disease (COPD). This study is being conducted by a group of clinical and academic experts from UK universities and Europe, together with pharmaceutical companies who have an interest in asthma. The sponsor of the study is the University of Leicester, UK. The sponsor is the organisation responsible for ensuring that the study is carried out correctly.

Who is funding the study?
Sanofi, the pharmaceutical company that makes dupilumab, is supporting the research by providing funding to the research units to carry out the study tests.

When is the study starting and how long is it expected to run for?
March 2023 to December 2026

Who is the main contact?
UK project management team, abc-3tr@leicester.ac.uk
Chief Investigator, Prof Chris Brightling, abc-3tr@leicester.ac.uk

Contact information

Type(s)
Public

Contact name
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Type(s)
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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
320731

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
UoL0870, IRAS 320731, CPMS 55224

Study information

Scientific Title
Biomarkers and mechanisms of asthma remission following treatment with dupilumab in adults with severe asthma – 3TR ABC

Acronym
DUPIBIO – 3TR ABC

Study objectives

Asthma remission following treatment with dupilumab is related to baseline phenotype and biomarker(s) or early changes in biomarkers.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 13/04/2023, East Midlands – Nottingham 1 (The Old Chapel, Royal Standard Place, Nottingham, NG1 6FS, United Kingdom; +44 207 104 8089; nottingham1.rec@hra.nhs.uk), ref: 23/EM/0031

Approved 13/04/2023, East Midlands - Nottingham Research Ethics Committee 1 (Health Research Authority, 2nd Floor, Equinox House, City link, Nottingham, NG2 4LA, UK; +44(0) 2078115; nottingham1.rec@hra.nhs.uk), ref: 23/EM/0031

Study design
Multi-centre, multi-national observational study

Primary study design
Observational

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Severe asthma

Interventions
DUPIBIO – 3TR ABC is a multi-centre observational study of patients with severe asthma following initiation of treatment with dupilumab (anti-IL4Rα) as part of their standard of care. Participants will be extensively characterised at baseline; reviewed throughout the year with formal clinical and biological assessment at 4, 16 and 52 weeks. Asthma remission will be defined for each domain: asthma control, lung function, and exacerbations as a composite measure and independently. Biomarkers and multi-omic analysis will be undertaken in the biosamples to determine biological pathways and bio-signatures associated with asthma remission. This study is one of three arms aligned to the 3TR (taxonomy, treatment, targets and remission) EU-IMI consortium asthma biologics consortium (3TR-ABC).

The primary objective is to determine baseline biomarkers of remission after 1 year of biological therapy, with remission defined as ACQ-5 <1.5, post-bronchodilator FEV1 percent predicted ≥80% OR >10% improvement, as well as no exacerbations.

The secondary objectives are to determine baseline and short-term biomarkers of long-term remission after 1 year of biological therapy. Additionally:
1. Change in biomarker profiles in remission versus non-remission groups
2. Baseline and change in biomarker profile for
2.1. Each response outcome individually
2.2. Global evaluation treatment efficacy (GETE), Patient and physician-rated response-defined response
2.3. The 3TR agreed composite assessment of response

2.4. Change in profiles from baseline to 4 and 16 weeks as a predictor of remission
3. Determine the change in all response variables against baseline biomarker data and change in biomarkers as continuous variables.

Intervention Type
Other

Primary outcome(s)
Primary outcome measures are assessed at 1 year:
1. Asthma control measured using the Asthma Control Questionnaire 5 Questions (ACQ5) <1.5
2. Lung function post-bronchodilator (post-BD) Forced Expiratory Volume in 1 Second (FEV1) percent predicted measured using spirometry
3. Exacerbations history measured using the patient's medical notes

Key secondary outcome(s))
Current secondary outcome measures as of 30/07/2024:

1. Patient-reported outcomes:
1.1. Asthma Control Questionnaire 5 Questions (ACQ5), assessed at visit 1 (week 0), visit 2 (week 4), visit 3 (week 16), visit 4 (week 52).
1.2. The Asthma Quality of Life Questionnaire (AQLQ), assessed at visit 1 (week 0), visit 2 (week 4), visit 3 (week 16), visit 4 (week 52).
1.3. Self-Assessment Questionnaire (SAQ), assessed at visit 1 (week 0), Visit 2 (week 4), visit 3 (week 16), visit 4 (week 52).
1.4. EQ5D5L health status questionnaire, assessed at visit 1 (week 0), visit 2 (week 4), visit 3 (week 16), visit 4 (week 52).
1.5. Work Productivity and Activity Impairment Questionnaire General Health (WPAI:GH), assessed visit 1 (week 0), visit 2 (week 4), visit 3 (week 16), visit 4 (week 52).
1.6. Sino-Nasal Outcome Test-22 Questionnaire (SNOT22), assessed visit 1 (week 0), visit 2 (week 4), visit 3 (week 16), visit 4 (week 52).
1.7. Nijmegen Questionnaire (NQ), assessed visit 1 (week 0), visit 2 (week 4), visit 3 (week 16), visit 4 (week 52).
1.8. Epworth Sleepiness Scale (ESS), assessed visit 1 (week 0), visit 2 (week 4), visit 3 (week 16), visit 4 (week 52).
1.9. Hospital Anxiety and Depression Scale (HADS), assessed visit 1 (week 0), visit 2 (week 2), visit 3 (week 16), visit 4 (week 52).
1.10. Functional Assessment of Chronic Illness Therapy (FACIT) fatigue scale, assessed at visit 1 (week 0), visit 2 (week 4), visit 3 (week 16), visit 4 (week 52).
1.11. Cognitive Failures Questionnaire, Screen for Cognitive Impairment in Psychiatry (SCIP), Trail Making test (TMT) part B (specific sites), assessed at visit 1 (week 0), visit 3 (week 16) and visit 4 (week 52).
1.12. Global evaluation treatment efficacy (GETE), patient and physician-related response, assessed at visit 2 (week 4), visit 3 (week 16), visit 4 (week 52).
1.13. Visual analogue scale (VAS) scale 3TR question (patient and physician perceived), assessed at visit 1 (week 0), visit 2 (week 4), visit 3 (week 16), visit 4 (week 52).
1.14. Symptoms VAS, assessed at visit 1 (week 0), visit 2 (week 4), visit 3 (week 16), visit 4 (week 52) and unscheduled exacerbation visit at sites where feasible/applicable.

2. Lung function:
2.1. Pre and post BD spirometry, assessed at visit 1 (week 0).
2.2. Post BD Forced Expiratory Volume in 1 Second (FEV1) assessed at visit 1 (week 0), visit 2

(week 4), visit 3 (week 16), visit 4 (week 52), and unscheduled exacerbation visit at sites where feasible/applicable.

3. Biomarkers:
3.1. Blood: differential cell count, total IgE and transcriptome (and in a subgroup scRNA), assessed at visit 1 (week 0), visit 2 (week 4), visit 3 (week 16), visit 4 (week 52). Specific IgE if not done with skin prick tests (cat dander, dog dander, house dust mite, grass pollen and Aspergillus IgE) and immunophenotyping, methylome (DNA collected for possible later eQTL analyses depending upon transcriptome data), assessed at visit 1 (week 0).
3.2. Nasal sampling: nasal brushings, assessed at visit 1 (week 0), visit 2 (week 4), visit 3 (week 16), visit 4 (week 52), and unscheduled exacerbation visit at sites where feasible/applicable.
3.3. Breath:
3.3.1. FeNO is assessed at visit 1 (week 0), visit 2 (week 4), visit 3 (week 16), visit 4 (week 52), and unscheduled exacerbation visit.
3.3.2. Breathomics is assessed at visit 1 (week 0), visit 2 (week 4), and visit 4 (week 52).
3.4. Sputum: cell differential, transcriptome, micro/metagenomics and proteomics, assessed at visit 1 (week 0), visit 2 (week 4), visit 3 (week 16), visit 4 (week 52), and unscheduled exacerbation visit at sites where feasible/applicable.
3.5. Saliva: Microbiome analysis and DNA, assessed at visit 1 (week 0), visit 2 (week 4), visit 3 (week 16), visit 4 (week 52), and unscheduled exacerbation visit at sites where feasible /applicable.
3.6. Urine: Urinary lipid mediators and metabolomics, assessed at visit 1 (week 0), visit 2 (week 4), visit 3 (week 16), visit 4 (week 52), and unscheduled exacerbation visit at sites where feasible /applicable.
3.7. Stool (optional): micro/metagenomics, assessed at visit 1 (week 0), visit 2 (week 4), visit 3 (week 16), visit 4 (week 52).
3.8. Bronchoscopy (optional): brush biopsy, bronchial biopsies and broncho-alveolar lavage (BAL) for transcriptome, protein, micro/metagenomics, cellular and structural analyses, assessed at visit 1 (week 0) and visit 4 (week 52).
3.9. Mucosal biopsies: histological analysis of cells and inflammatory mediators, assessed at visit 1 (week 0), visit 2 (week 4), visit 3 (week 16), visit 4 (week 52).

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Previous secondary outcome measures as of 19/01/2024:

1. Patient-reported outcomes:
1.1. Asthma Control Questionnaire 5 Questions (ACQ5), assessed at visit 1 (week 0), visit 2 (week 4), visit 3 (week 16), visit 4 (week 52).
1.2. The Asthma Quality of Life Questionnaire (AQLQ), assessed at visit 1 (week 0), visit 2 (week 4), visit 3 (week 16), visit 4 (week 52).
1.3. Self-Assessment Questionnaire (SAQ), assessed at visit 1 (week 0), Visit 2 (week 4), visit 3 (week 16), visit 4 (week 52).
1.4. EQ5D5L health status questionnaire, assessed at visit 1 (week 0), visit 2 (week 4), visit 3 (week 16), visit 4 (week 52).
1.5. Work Productivity and Activity Impairment Questionnaire General Health (WPAI:GH), assessed visit 1 (week 0), visit 2 (week 4), visit 3 (week 16), visit 4 (week 52).
1.6. Sino-Nasal Outcome Test-22 Questionnaire (SNOT22), assessed visit 1 (week 0), visit 2 (week 4), visit 3 (week 16), visit 4 (week 52).
1.7. Nijmegen Questionnaire (NQ), assessed visit 1 (week 0), visit 2 (week 4), visit 3 (week 16), visit 4 (week 52).
1.8. Epworth Sleepiness Scale (ESS), assessed visit 1 (week 0), visit 2 (week 4), visit 3 (week 16),

visit 4 (week 52).
1.9. Hospital Anxiety and Depression Scale (HADS), assessed visit 1 (week 0), visit 2 (week 2), visit 3 (week 16), visit 4 (week 52).
1.10. Functional Assessment of Chronic Illness Therapy (FACIT) fatigue scale, assessed at visit 1 (week 0), visit 2 (week 4), visit 3 (week 16), visit 4 (week 52).
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1.12. Global evaluation treatment efficacy (GETE), patient and physician-related response, assessed at visit 2 (week 4), visit 3 (week 16), visit 4 (week 52).
1.13. Visual analogue scale (VAS) scale 3TR question (patient and physician perceived), assessed at visit 1 (week 0), visit 2 (week 4), visit 3 (week 16), visit 4 (week 52).
1.14. Symptoms VAS, assessed at visit 1 (week 0), visit 2 (week 4), visit 3 (week 16), visit 4 (week 52) and unscheduled exacerbation visit at sites where feasible/applicable.

2. Lung function:
2.1. Pre and post BD spirometry, assessed at visit 1 (week 0).
2.2. Post BD Forced Expiratory Volume in 1 Second (FEV1) assessed at visit 1 (week 0), visit 2 (week 4), visit 3 (week 16), visit 4 (week 52), and unscheduled exacerbation visit at sites where feasible/applicable.

3. Biomarkers:
3.1. Blood: differential cell count, total IgE and transcriptome (and in a subgroup scRNA), assessed at visit 1 (week 0), visit 2 (week 4), visit 3 (week 16), visit 4 (week 52). Specific IgE if not done with skin prick tests (cat dander, dog dander, house dust mite, grass pollen and Aspergillus IgE) and immunophenotyping, methylome (DNA collected for possible later eQTL analyses depending upon transcriptome data), assessed at visit 1 (week 0).
3.2. Nasal sampling: nasal brushings, assessed at visit 1 (week 0), visit 2 (week 4), visit 3 (week 16), visit 4 (week 52), and unscheduled exacerbation visit at sites where feasible/applicable.
3.3. Breath: Fractional exhaled nitric oxide (FeNO) and breathomics, assessed at visit 1 (week 0), visit 2 (week 4), visit 3 (week 16), visit 4 (week 52).
3.4. Sputum: cell differential, transcriptome, micro/metagenomics and proteomics, assessed at visit 1 (week 0), visit 2 (week 4), visit 3 (week 16), visit 4 (week 52), and unscheduled exacerbation visit at sites where feasible/applicable.
3.5. Saliva: Microbiome analysis and DNA, assessed at visit 1 (week 0), visit 2 (week 4), visit 3 (week 16), visit 4 (week 52), and unscheduled exacerbation visit at sites where feasible /applicable.
3.6. Urine: Urinary lipid mediators and metabolomics, assessed at visit 1 (week 0), visit 2 (week 4), visit 3 (week 16), visit 4 (week 52), and unscheduled exacerbation visit at sites where feasible /applicable.
3.7. Stool (optional): micro/metagenomics, assessed at visit 1 (week 0), visit 2 (week 4), visit 3 (week 16), visit 4 (week 52).
3.8. Bronchoscopy (optional): brush biopsy, bronchial biopsies and broncho-alveolar lavage (BAL) for transcriptome, protein, micro/metagenomics, cellular and structural analyses, assessed at visit 1 (week 0) and visit 4 (week 52).
3.9. Mucosal biopsies: histological analysis of cells and inflammatory mediators, assessed at visit 1 (week 0), visit 2 (week 4), visit 3 (week 16), visit 4 (week 52).

Previous secondary outcome measures as of 09/08/2023:

1. Patient-reported outcomes:
1.1. Asthma Control Questionnaire 5 Questions (ACQ5), assessed at visit 1 (week 0), visit 3 (week 16), visit 4 (week 52), and unscheduled exacerbation visit at sites where feasible/applicable.
1.2. The Asthma Quality of Life Questionnaire (AQLQ), assessed at visit 1 (week 0), visit 3 (week 16), visit 4 (week 52).
1.3. Self-Assessment Questionnaire (SAQ), assessed at visit 1 (week 0), visit 3 (week 16), visit 4 (week 52).
1.4. EQ5D5L health status questionnaire, assessed at visit 1 (week 0), visit 3 (week 16), visit 4 (week 52).
1.5. Work Productivity and Activity Impairment Questionnaire General Health (WPAI:GH), assessed visit 1 (week 0), visit 3 (week 16), visit 4 (week 52).
1.6. Sino-Nasal Outcome Test-22 Questionnaire (SNOT22), assessed visit 1 (week 0), visit 3 (week 16), visit 4 (week 52).
1.7. Nijmegen Questionnaire (NQ), assessed visit 1 (week 0), visit 3 (week 16), visit 4 (week 52).
1.8. Epworth Sleepiness Scale (ESS), assessed visit 1 (week 0), visit 3 (week 16), visit 4 (week 52).
1.9. Hospital Anxiety and Depression Scale (HADS), assessed visit 1 (week 0), visit 3 (week 16), visit 4 (week 52).
1.10. Functional Assessment of Chronic Illness Therapy (FACIT) fatigue scale, assessed at visit 1 (week 0), visit 3 (week 16), visit 4 (week 52).
1.11. Cognitive Failures Questionnaire, Screen for Cognitive Impairment in Psychiatry (SCIP), Trail Making test (TMT) (specific sites), assessed at visit 1 (week 0), visit 3 (week 16) and visit 4 (week 52).
1.12. Global evaluation treatment efficacy (GETE), patient and physician-related response, assessed at visit 1 (week 0), visit 2 (week 4), visit 3 (week 16), visit 4 (week 52).
1.13. Visual analogue scale (VAS) scale 3TR question (patient and physician perceived), assessed at visit 1 (week 0), visit 2 (week 4), visit 3 (week 16), visit 4 (week 52).

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2.1. Pre and post BD spirometry, assessed at visit 1 (week 0).
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3.4. Sputum: cell differential, transcriptome, micro/metagenomics and proteomics, assessed at visit 1 (week 0), visit 2 (week 4), visit 3 (week 16), visit 4 (week 52), and unscheduled exacerbation visit at sites where feasible/applicable.
3.5. Oral gargle: Microbiome analysis, assessed at visit 1 (week 0), visit 2 (week 4), visit 3 (week 16), visit 4 (week 52), and unscheduled exacerbation visit at sites where feasible/applicable.
3.6. Urine: Urinary lipid mediators and metabolomics, assessed at visit 1 (week 0), visit 2 (week 4), visit 3 (week 16), visit 4 (week 52), and unscheduled exacerbation visit at sites where feasible /applicable.
3.7. Stool (optional): micro/metagenomics, assessed at visit 1 (week 0), visit 2 (week 4), visit 3

(week 16), visit 4 (week 52).
3.8. Bronchoscopy (optional): brush biopsy, bronchial biopsies and broncho-alveolar lavage (BAL) for transcriptome, protein, micro/metagenomics, cellular and structural analyses, assessed at visit 1 (week 0) and visit 4 (week 52).
3.9. Mucosal biopsies: histological analysis of cells and inflammatory mediators, assessed at visit 1 (week 0), visit 2 (week 4), visit 3 (week 16), visit 4 (week 52).

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1. Patient-reported outcomes:
1.1. Asthma Control Questionnaire 5 Questions (ACQ5), assessed at visit 1 (week 0), visit 2 (week 4), visit 3 (week 16), visit 4 (week 52), and unscheduled exacerbation visit at sites where feasible /applicable.
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1.5. Work Productivity and Activity Impairment Questionnaire (WPAI), assessed visit 1 (week 0), visit 2 (week 4), visit 3 (week 16), visit 4 (week 52).
1.6. Sino-Nasal Outcome Test-22 Questionnaire (SNOT22), assessed visit 1 (week 0), visit 2 (week 4), visit 3 (week 16), visit 4 (week 52).
1.7. Nijmegen Questionnaire (NQ), assessed visit 1 (week 0), visit 2 (week 4), visit 3 (week 16), visit 4 (week 52).
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3.2. Nasal sampling: nasal brushings, assessed at visit 1 (week 0), visit 2 (week 4), visit 3 (week 16), visit 4 (week 52), and unscheduled exacerbation visit at sites where feasible/applicable.
3.3. Breath: Fractional exhaled nitric oxide (FeNO) and breathomics, assessed at visit 1 (week 0), visit 2 (week 4), visit 3 (week 16), visit 4 (week 52).
3.4. Sputum: cell differential, transcriptome, micro/metagenomics and proteomics, assessed at visit 1 (week 0), visit 2 (week 4), visit 3 (week 16), visit 4 (week 52), and unscheduled exacerbation visit at sites where feasible/applicable.
3.5. Oral gargle: Microbiome analysis, assessed at visit 1 (week 0), visit 2 (week 4), visit 3 (week 16), visit 4 (week 52), and unscheduled exacerbation visit at sites where feasible/applicable.
3.6. Urine: Urinary lipid mediators and metabolomics, assessed at visit 1 (week 0), visit 2 (week 4), visit 3 (week 16), visit 4 (week 52), and unscheduled exacerbation visit at sites where feasible /applicable.
3.7. Stool (optional): micro/metagenomics, assessed at visit 1 (week 0), visit 2 (week 4), visit 3 (week 16), visit 4 (week 52).
3.8. Bronchoscopy (optional): brush biopsy, bronchial biopsies and broncho-alveolar lavage (BAL) for transcriptome, protein, micro/metagenomics, cellular and structural analyses, assessed at visit 1 (week 0) and visit 4 (week 52).
3.9. Mucosal biopsies: histological analysis of cells and inflammatory mediators, assessed at visit 1 (week 0), visit 2 (week 4), visit 3 (week 16), visit 4 (week 52).

Completion date
31/12/2026

Eligibility

Key inclusion criteria
1. Adults (≥18 years old)
2. Clinical decision to initiate dupilumab for severe asthma after meeting licensing, local and national guidelines.
3. Be able to give valid written consent. Participants should have reasonable understanding of the English language (assessed by the research team)
4. Be compliant with study procedures and study visits.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria

1. Known hypersensitivity to the active substance of dupilumab or any of the excipients
2. Participation in an interventional clinical trial within 3 months of visit 1 or receipt of any investigational medicinal product within 3 months or 5 half-lives. Participation in other observational studies is acceptable if, in the view of the investigator, it will not impact the study outcomes.
3. Other clinically significant medical disease or uncontrolled concomitant disease that is likely, in the opinion of the investigator, to require a change in therapy or impact the ability to participate in the study.
4. Subjects on regular oral corticosteroids (OCS) and whereby the administration of dupilumab for OCS reduction will not be included in the study.

Date of first enrolment
31/08/2023

Date of final enrolment
31/12/2025

Locations

Countries of recruitment
United Kingdom

England

Northern Ireland

Scotland

Study participating centre
University Hospitals of Leicester NHS Trust
Glenfield Hospital
Groby Rd
Leicester
Leicester
United Kingdom
LE3 9QP

Study participating centre
Manchester University NHS Foundation Trust
Cobbett House
Oxford Road
Manchester
United Kingdom
M13 9WL

Study participating centre
NHS Greater Glasgow and Clyde
J B Russell House
Gartnavel Royal Hospital
1055 Great Western Road Glasgow
Glasgow
United Kingdom
G12 0XH

Study participating centre
University Hospital Southampton NHS Foundation Trust
Southampton General Hospital
Tremona Road
Southampton
United Kingdom
SO16 6YD

Study participating centre
Belfast Health and Social Care Trust
Trust Headquarters
A Floor - Belfast City Hospital
Lisburn Road
Belfast
United Kingdom
BT9 7AB

Study participating centre
Guy's and St Thomas' NHS Foundation Trust
Sydney Street
London
United Kingdom
SW3 6NP

Study participating centre
Cambridge University Hospitals NHS Foundation Trust
Cambridge Biomedical Campus
Hills Road
Cambridge
United Kingdom
CB2 0QQ

Sponsor information

Organisation
University of Leicester

ROR
https://ror.org/04h699437

Funder(s)

Funder type
Industry

Funder Name
Sanofi

Alternative Name(s)
sanofi-aventis, Sanofi US, Sanofi-Aventis U.S. LLC, Sanofi U.S.

Funding Body Type
Government organisation

Funding Body Subtype
For-profit companies (industry)

Location
United States of America

Results and Publications

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

IPD sharing plan summary
Published as a supplement to the results publication

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			26/07/2023	No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes