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Investigating the effect of the pro-inflammatory messenger interleukin-5 on antibody-secreting immune cells in the nose

Submission date
15/04/2024

Recruitment status
No longer recruiting

Registration date
26/06/2024

Overall study status
Ongoing

Last Edited
11/03/2025

Condition category
Ear, Nose and Throat

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

Plain English summary of protocol

Background and study aims
In patients with asthma, nasal polyps and other similar diseases, the chemical messenger interleukin-5 (IL-5) in the body is known to have an important role in causing disease - blocking the IL-5 message improves disease control and can lead to clinical remission. IL-5 is often thought to work through its actions on a type of immune cell called eosinophils, but there is evidence it may also have important actions on other types of immune cells. In particular it appears to have actions on antibody-producing B cells. This study will investigate how IL-5 affects antibody expression by B cells in the nose using samples collected from patients undergoing removal of tissue samples from the nose for clinical reasons.

Who can participate?
Patients aged 18 years and over having surgery to remove nasal tissue for clinical reasons at relevant NHS sites

What does the study involve?
The study involves donating to the research project the nasal samples that are being removed at clinically planned surgery. The study team will also collect some clinical data, a sample of blood and a sample of the fluid inside the nose using a special sponge (certain NHS sites only).

What are the possible benefits and risks of participating?
There are minimal risks from participating as the major study activity is the donation to research of the nasal samples being removed from the nose by surgeons as part of planned clinical care. The study will not directly benefit participating patients but will help develop better treatments for patients with these conditions.

Where is the study run from?
Queen Mary University of London (UK)

When is the study starting and how long is it expected to run for?
February 2023 to January 2029

Who is funding the study?
The study was designed and is being run by academics at Queen Mary University of London but is funded as an investigator-initiated study by GlaxoSmithKline (UK)

Who is the main contact?
Dr Paul Pfeffer, Paul.pfeffer1@nhs.net

Contact information

Type(s)
Scientific

Contact name
Dr Paul Pfeffer

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
332970

Protocol serial number
CPMS 60796, IRAS 332970

Study information

Scientific Title
Investigating pro-inflammatory B-lymphocyte responses in nasal polyps to interleukin-5

Acronym
BLYNI5

Study objectives
The researchers hypothesise that anti-IL-5 monoclonal antibody therapy may have clinical action in asthma and nasal polyps through effects on other cell types than just eosinophils and potentially much of the beneficial effect of blocking IL-5 may be due to the effects on these

other cell types. Specifically, they hypothesise that IL-5 exerts disease-relevant actions on antibody production by B lymphocytes in airway tissue such as nasal polyps.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 06/02/2024, London - City & East Research Ethics Committee (Research Ethics Committee Centre, 2nd Floor, 2 Redman Place, Stratford, London, E20 1JQ, UK; +44 (0)207 1048171, +44 (0)207 1048134, +44 (0)207 104 8124; cityandeast.rec@hra.nhs.uk), ref: 24/PR/0073

Study design
Observational; Design type: Clinical Laboratory Study

Primary study design
Observational

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Nasal polyps

Interventions
Patients undergoing resection of nasal polyps and/or turbinates for clinical reasons by ENT surgeons at NHS research sites will be invited by their clinical care teams to consider donating resected nasal tissue for use in this research project. Interested patients will be given Patient Information Sheets, detailing the reason for the research and what is involved, in advance of the surgery, to enable them to give informed consent to participate. The clinical care of patients and the amount of tissue resected will not be affected by their decision on whether or not to participate in this research.

Resected nasal tissue from patients who consent to participate will be used in immunological experiments as below. The clinical notes of consented participants will also be reviewed to obtain relevant past medical details - any past history of asthma, allergic or inflammatory diseases including smoking status; the reasons for the nasal surgery; any relevant medications the participant is taking; and any previous immunology test results. The patient's age, gender, ethnicity and BMI will also be recorded. When these questions are not clearly answered in the medical notes, the patient will be asked the questions.

Participants may also be asked if they consent to give a sample of blood for immunological investigations and whether they are willing to give a nasal sponge/filter paper sample of their nasal lining fluid secretions (nasoabsorption sample). Participants can decline these but still give their residual nasal tissue for the study. All clinical data and laboratory investigations will be recorded in an anonymised manner to maintain patient confidentiality.

All participant involvement will be limited to the single clinical care episode during which they have nasal surgery. Laboratory science immunological experiments will be conducted with the nasal tissue samples. Additionally, blood samples may be used to compare circulating cells with those present in nasal tissue.

Intervention Type
Other

Phase
Not Specified

Primary outcome(s)
The B cell receptor (BCR) (antibody immunoglobulin) repertoire of tissue-resident airway B-cells, in particular the relative expression of different immunoglobulin classes and subclasses. Measured using single-cell and bulk RNA sequencing at baseline.

Key secondary outcome(s))
BCR repertoires for convergent clonotypes evident in blood (from IDEA project) and other available BCR libraries, to assess for potential pathological clonotypes in eosinophilic airway inflammation. Measured using single-cell and bulk RNA sequencing at baseline.

Completion date
11/01/2029

Eligibility

Key inclusion criteria
1. Patients undergoing resection of nasal tissue for clinical indications (e.g. polypectomy, turbinectomy, septoplasty, tonsilectomy)
2. Able to give consent
3. Aged 18 years and over

The researchers will specifically recruit the following subgroups:
1. Patients undergoing nasal polyp resections, who are not on biologics
2. Patients undergoing nasal polyp resections, who are on anti-IL-5 biologics
3. Patients undergoing nasal operations other than polyp resection

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
1. Inability to give consent
2. Previous rituximab treatment (ever)

3. Chemotherapy with preceding 6 months
4. Cystic fibrosis
5. Pregnancy or breastfeeding
6. Known current COVID infection/TB infection

Date of first enrolment
14/03/2024

Date of final enrolment
31/12/2025

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Royal London Hospital
Whitechapel Road
London
United Kingdom
E1 1FR

Study participating centre
Homerton Hospital
Homerton Row
London
United Kingdom
E9 6SR

Study participating centre
Uclh
250 Euston Road
London
United Kingdom
NW1 2PQ

Study participating centre
Guys Hospital
Guys Hospital
Great Maze Pond

London
United Kingdom
SE1 9RT

Sponsor information

Organisation
Queen Mary University of London

ROR
https://ror.org/026zzn846

Funder(s)

Funder type
Industry

Funder Name
GlaxoSmithKline; Grant Codes: 220761

Alternative Name(s)
GlaxoSmithKline plc., GSK plc., GlaxoSmithKline plc, GSK

Funding Body Type
Government organisation

Funding Body Subtype
For-profit companies (industry)

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
The data-sharing plans for the current study are unknown and will be made available at a later date

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	version 2	09/02/2024	18/04/2024	No	Yes
Protocol file	version 1.1	02/01/2024	18/04/2024	No	No