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Lung magnetic resonance imaging (MRI) in people with asthma

Submission date
06/06/2025

Recruitment status
Recruiting

Registration date
10/06/2025

Overall study status
Ongoing

Last Edited
19/06/2025

Condition category
Respiratory

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Asthma is a lung condition that causes symptoms like coughing, wheezing, and shortness of breath. This study aims to better understand how asthma affects the lungs over time and how treatments can improve breathing. To do this, researchers are using advanced imaging methods to look closely at how the lungs work and how their structure changes over time. The study includes participants from a study called ETHA (Evaluation of Triple Therapy Using Magnetic Resonance Imaging in Asthma), who provided written informed consent for this study, in order to capture longer-term follow-up information.

Who can participate?
Patients aged 18-85 years with eosinophilic asthma (a rare type of asthma)

What does the study involve?
The investigators will apply 129Xenon and/or 3He image acquisition and analysis methods in 200 asthma patient volunteers in order to characterize and probe the relationship between lung structure and function using imaging.
Participants will undergo a series of assessments over time to capture longitudinal data. These assessments include vital signs, lung function tests, and MRI scans performed both before and after administration of four puffs (100 mcg each) of a bronchodilator, followed by 15 minutes of rest. Participants also complete respiratory and health-related questionnaires after the post-bronchodilator assessments. In addition, a chest CT scan may be performed at each visit.

What are the possible benefits and risks of participating?
Since this study does not provide treatment, there is no direct benefit to the participants. Information learned from the study may help other people with asthma in the future.

Where is the study run from?
Robarts Research Institute, Western University (Canada)

When is the study starting and how long is it expected to run for?
March 2013 to December 2038

Who is funding the study?
Partially funded by GlaxoSmithKline

Who is the main contact?
Dr Grace Parraga, gparraga@uwo.ca

Contact information

Type(s)
Public, Scientific, Principal investigator

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Additional identifiers

ClinicalTrials.gov (NCT)
NCT02351141

Protocol serial number
ROB0037

Study information

Scientific Title
Structure and function MRI of asthma

Study objectives
The study aims to understand the relationship between regional lung structure and function in individuals with asthma using advanced imaging techniques (e.g., hyperpolarized gas MRI) and pulmonary function tests. By tracking participants over time, the study seeks to assess how structural and functional changes in the lungs correlate with asthma control, severity, and progression, thereby providing insight into the mechanisms of airway remodeling and heterogeneity in asthma.

Ethics approval required
Ethics approval required

Ethics approval(s)

1. Approved 08/03/2013, Western University Research Ethics Board (1393 Western Road, London, N6G 0V7, Canada; +1 (0)519 661 3036; ethics@uwo.ca), ref: Project ID: 103516

2. Approved 20/11/2024, Western University Research Ethics Board (1393 Western Road, London, N6G 0V7, Canada; +1 (0)519 661 3036; ethics@uwo.ca), ref: Project ID: 103516

Primary study design
Observational

Study design
Single-centre observational longitudinal cohort study

Study type(s)
Other

Health condition(s) or problem(s) studied
Asthma

Interventions
Single-centre observational longitudinal cohort study, assessing structural and functional lung changes in asthma patients using hyperpolarized gas MRI and other respiratory assessments. In order to capture longitudinal data for the "Evaluation of triple therapy using magnetic resonance imaging in asthma (ETHA)" study (ISRCTN18210817), participants provided written informed consent to this open asthma study.

The study follows participants with asthma over a 15-year period to evaluate structural and functional lung changes. Participants undergo a series of assessments at baseline, including hyperpolarized gas MRI (^{3}He and/or ^{129}Xe), chest CT, pulmonary function tests (spirometry, plethysmography), airwave oscillometry, fractional exhaled nitric oxide (FeNO), lung clearance index (LCI), and symptom scoring using the BORG and MRC Dyspnea Scales. Participants are offered optional annual follow-up visits, up to 10 times, to monitor changes over time using the same assessments.

Intervention Type
Other

Primary outcome(s)
Ventilation Defect Percent as measured by Xenon-129 and/or Helium-3 MRI at baseline and as frequently as annually for up to 10 years for each participant

Key secondary outcome(s)
Forced Expiratory Volume (FEV1) measured by spirometry at baseline and as frequently as annually for up to 10 years for each participant

Completion date
31/12/2038

Eligibility

Key inclusion criteria

1. Male and female patients aged 18-85 years with a clinical diagnosis of asthma
2. Smoking history ≤1 pack/year
3. Understands the study procedures and is willing to participate in the study as indicated by signature on the informed consent
4. Judged to be in otherwise stable health on the basis of medical history
5. Able to perform reproducible pulmonary function testing (i.e., the three best acceptable spirograms have FEV1 values that do not vary more than 5% of the largest value or more than 100 ml, whichever is greater)
6. FEV1 >60% predicted

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Upper age limit
85 Years

Sex
All

Key exclusion criteria
1. Patient is, in the opinion of the investigator, mentally or legally incapacitated, preventing informed consent from being obtained, or cannot read or understand the written material
2. Patient is unable to perform spirometry or plethysmography maneuvers
3. Patient has an implanted mechanically, electrically or magnetically activated device or any metal in their body which cannot be removed, including but not limited to pacemakers, neurostimulators, biostimulators, implanted insulin pumps, aneurysm clips, bioprosthesis, artificial limb, metallic fragment or foreign body, shunt, surgical staples (including clips or metallic sutures and/or ear implants). (At the discretion of the MRI Technologist/3T Manager)
4. In the investigator’s opinion, the patient suffers from any physical, psychological or other condition(s) that might prevent performance of the MRI, such as severe claustrophobia
5. Patient is pregnant

Date of first enrolment
04/01/2015

Date of final enrolment
31/12/2028

Locations

Countries of recruitment

Canada

Study participating centre
Robarts Research Institute, Western University
1151 Richmond Street North
London
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Sponsor information

Organisation
Western University (Canada)

Funder(s)

Funder type
Industry

Funder Name
GlaxoSmithKline

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 datasets generated and/or analyzed during the current study will be available upon request from Dr Grace Parraga (gparraga@uwo.ca). Data is anonymized; written informed consent was provided by all participants; data will be available starting today for 5 years; all research data are available except for age and sex.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Basic results			19/06/2025	No	No
Protocol file	version 16	15/11/2024	10/06/2025	No	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes