# Manchester Asthma and Allergy Study (MAAS) age 25 plus follow up

| Submission date   | Recruitment status  Not yet recruiting                       | [X] Prospectively registered    |  |  |
|-------------------|--|---------------------------------|--|--|
| 11/08/2025        |  | [X] Protocol                    |  |  |
| Registration date | Overall study status Ongoing  Condition category Respiratory | Statistical analysis plan       |  |  |
| 26/08/2025        |  | Results                         |  |  |
| Last Edited       |  | Individual participant data     |  |  |
| 22/08/2025        |  | [X] Record updated in last year |  |  |

#### Plain English summary of protocol

Background and study aims

Asthma is the most common long-term illness in children, but we still don't fully understand what causes it. It tends to run in families, but it's not linked to a single gene, and environmental factors like pollution, allergens, tobacco smoke and viruses also play a role. Most asthma begins early in life, and researchers believe it's caused by a mix of genetic and environmental factors. This study builds on a long-running research project called the Manchester Asthma and Allergy Study (MAAS), which has followed children born in the mid-1990s to learn more about asthma. The aim now is to invite these participants, who are now adults aged 25 and over, to take part in a new follow-up to help researchers understand why asthma continues into adulthood for some people.

#### Who can participate?

People who were part of the original MAAS birth cohort study, recruited from Wythenshawe and Stepping Hill Hospitals in 1995, are being invited to take part.

#### What does the study involve?

Participants will be asked to attend a single visit lasting about 2 hours. This can take place at Wythenshawe Hospital, at home, or online/by post if preferred. During the visit, they'll complete questionnaires and have lung function and blood tests.

What are the possible benefits and risks of participating?

There are no direct medical benefits to taking part, but the information collected could help improve understanding of asthma and lead to better treatments in the future. The risks are minimal and similar to those of routine medical tests, such as a small amount of discomfort during blood sampling.

Where is the study run from?
Wythenshawe Hospital in Manchester (UK)

When is the study starting and how long is it expected to run for? July 2024 to May 2028

Who is funding the study? North West Lung Centre Charity (UK)

Who is the main contact? Prof Clare Murray, clare.murray@manchester.ac.uk

# Contact information

#### Type(s)

Public, Scientific, Principal investigator

#### Contact name

Prof Clare Murray

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# Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

**Integrated Research Application System (IRAS)** 

351417

ClinicalTrials.gov (NCT)

Nil known

Protocol serial number

Nil known

# Study information

#### Scientific Title

Manchester Asthma and Allergy Study (MAAS) age 25 plus follow up

#### **Acronym**

MAAS25

#### **Study objectives**

Primary Question/Objective:

To identify the predictors of and risk factors for persistence of childhood asthma

#### Secondary Question/Objective:

- 1. To investigate the genetic, environmental and temporal factors which predict lung function, asthma and phenotypes and endotypes of wheeze
- 2. To determine predictors and biomarkers for development of lung function deficits into young adult life (e.g. CC16).
- 3. To investigate the genetic, environmental and temporal factors which predict onset and persistence of eczema, hay fever and food allergies
- 4. To investigate the determinants of symptom severity and exacerbations of wheezing illness.
- 5. To investigate the molecular mechanisms underlying genetic, environmental and temporal factors which predict onset and persistence and severity of eczema, hay fever, food allergies and exacerbations of wheezing illness.
- 6. To describe the patterns of sensitisation (to inhalant and food allergens) through childhood to adulthood and determine their associates
- 7. To model indoor and outdoor pollutants in relation to wheeze and atopic outcomes
- 8. To validate the clinical outcomes collected from questionnaire data with information collected

from the GP record (such as prescriptions issued and hospital attendances)

- 9. To identify determinants of circulating CC16 from birth to adulthood.
- 10. To describe the association between self-reported ADHD symptoms and asthma and other allergies, and explore associated genetic, environmental and temporal factors.

#### Ethics approval required

Ethics approval required

#### Ethics approval(s)

submitted 19/08/2025, South Central – Oxford B Research Ethics Committee (2 Redman Place, Stratford, London, E20 1JQ, United Kingdom; +44 207 104 8243; oxfordb.rec@hra.nhs.uk), ref: 25/SC/0291

#### Study design

Longitudinal birth cohort study

#### Primary study design

Observational

#### Study type(s)

Other

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

Asthma and allergic diseases

#### **Interventions**

The study will comprise a single visit lasting approximately 2 hours. During the visit the study participants will complete questionnaires, lung function tests, skin prick tests and have blood taken. In order to take part in the study, it is necessary to complete the questionnaires. All other tests are optional. Tests include:

Height, weight and body composition; blood pressure, heart rate and pulse oximetry. Skin prick testing to a panel of inhalant and food allergens (including house dust mite, cat, dog, grass, trees, mould, milk, egg, peanut, hazelnut, walnut, Brazil nut, cashew and peach). Lung function

- a. Fractional Exhaled nitric oxide (FeNO)- a non-invasive method of evaluating airway inflammation.
- b. Airways Oscillometry Airways resistance and reactance will be measured using the THORASYS tremoFlo® or similar, in accordance with department SOP. In brief, participants will be seated with their head in the neutral position. Wearing a nose-clip, participants will be instructed to firmly hold their cheeks, as to minimize the upper airway shunt artefact, and breathe tidally through the device. Measurements consist of 16 seconds recordings and the procedure will be repeated in triplicate.
- c. Airway resistance and static lung volumes will be measured pre and post bronchodilator, using whole body plethysmography, to assess airway calibre, total lung capacity and air trapping. This is a highly sensitive and accurate method of measuring lung function and provides essential diagnostic information. We have previously performed these tests at age 13-16 years. d. Spirometry and bronchodilator reversibility: Spirometry enables us to measure the volume and flow generated by a forced expiration and has been done at each visit since age 5 years. Flow measurements as they relate to lung volume give an indication of any flow limitation in the small airways. Measurement of spirometry before and after the administration of a bronchodilator (400µg salbutamol via a metered dose inhaler and large volume spacer) is the

most commonly used test for the diagnosis and monitoring of lung disease. Where possible, participants who do not want to attend clinic and are too far away for a home visit (see below) will be offered the opportunity to perform home spirometry following video training on the technique, with a spirometer that will be posted to the participant (subject to equipment being available).

Questionnaires regarding current and previous asthma and allergy symptoms, exacerbations, medications, hospital admissions and diagnoses will be asked.

- e. Respiratory Questionnaire, based on the European Community Respiratory Health Survey Questionnaire (ECRHS), with additional questions from International study of Asthma and Allergies in childhood (ISAAC) for continuity, and previous asthma exacerbations and prescriptions, where participants will be asked to check on the NHS app where possible. f. Health Survey– SF-12.
- g. food allergy questionnaire (based on the EUROPREVALL questionnaire).
- h. Asthma Control Test (ACT).
- i. Adult ADHD self-report Scale (ASRS).

Outdoor Environment and Pollution Monitoring questionnaire (previously administered at age 10-12 years; a short questionnaire about where participants lived and went to school during childhood, so that we can model exposure to pollutants and the effects on lung function and asthma).

Up to 20mls of blood will be taken by the research team. This will be collected in the clinic for a clinic visit and at home for a home visit. The measurement of the FBC will be done in the clinical laboratories at Wythenshawe Hospital (MFT, the site of the study visit). The remaining sample will be processed in the research laboratories at Wythenshawe Hospital (MFT) and stored in the freezers pending further analysis or shipment. This will be for measurement of IgE, RNA and proteins (including CC16). Cells will be separated so that peripheral blood mononuclear cells (PBMCs) can either be analysed immediately or cryopreserved in liquid nitrogen for future cell culture and functional studies. Aliquots will be sent securely packaged via courier to research collaborators with whom we will have a Material Transfer Agreement, in the UK and abroad, once funding for this work has been secured. Samples will be shared in line with contractual requirements for analysis for this study where collaborators have not yet been identified Data analysis will be conducted by University of Manchester Researchers and also by collaborators at Imperial College London, and University of Arizona, with whom we will have Material Transfer Agreements.

GP information: Participants will be asked to consent for the research team to access their primary care records to extract information on healthcare utilisation, diagnoses and medication prescriptions (this has been done previously up to age 10 years, and consent was sought at age 18+ years).

An Equality, Diversity and Inclusion (EDI) survey. This will not be linked to the research data but will be stored anonymously.

#### Intervention Type

Other

## Primary outcome(s)

Prevalence of asthma in the cohort, as defined by responses to the respiratory questionnaire measured at a single time point

## Key secondary outcome(s))

Measured at a single time point:

- 1. Prevalence of eczema, hay fever and food allergy as defined by questionnaires
- 2. Prevalence of allergy to inhalant allergens (dust mite cat and dog and pollen) and to foods

- 3. Classes of trajectories of measures of lung function (to identify predictors)
- 4. Classes of wheezing illness defined by frequency of episodes and exacerbations
- 5. Measurement of CC16 in relation to asthma and lung function outcomes
- 6. Classes of exposure to outdoor air pollutants to relate to clinical outcomes

#### Completion date

31/05/2028

# **Eligibility**

#### Key inclusion criteria

Membership of MAAS Birth Cohort

### Participant type(s)

Other

## Healthy volunteers allowed

No

#### Age group

Adult

#### Lower age limit

24 years

#### Upper age limit

34 years

#### Sex

All

#### Key exclusion criteria

Not member of MAAS birth cohort

#### Date of first enrolment

01/12/2025

#### Date of final enrolment

01/12/2027

# Locations

#### Countries of recruitment

**United Kingdom** 

England

#### Study participating centre

#### Wythenshawe Hospital

Southmoor Road Wythenshawe Manchester United Kingdom M23 9LT

# Sponsor information

## Organisation

University of Manchester

#### **ROR**

https://ror.org/027m9bs27

# Funder(s)

#### Funder type

Charity

#### Funder Name

North West Lung Centre Charity

# **Results and Publications**

#### Individual participant data (IPD) sharing plan

The datasets generated during the current study will be available upon request from clare. murray@manchester.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 |                               | 30/05/2025   | 22/08/2025 | No             | Yes             |
| Participant information sheet | Participant information sheet | 11/11/2025   | 11/11/2025 | No             | Yes             |
| Protocol file                 | Studywobsito                  | 08/04/2025   | 22/08/2025 | No             | No              |
| Study website                 |                               | 11/11/2025   | 11/11/2025 | No             | Yes             |