ISRCTN67658695 https://doi.org/10.1186/ISRCTN67658695

Asthma-Dx: A platform for investigating novel diagnostic techniques to improve asthma diagnosis in primary care

Submission date
09/02/2026

Recruitment status
Recruiting

Registration date
30/04/2026

Overall study status
Ongoing

Last Edited
11/05/2026

Condition category
Respiratory

[ ] Prospectively registered
[ ] 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 lung condition where the airways can become narrowed and inflamed, causing coughing, breathlessness and wheezing, which vary over time. At the moment, there is no single test that can say whether someone has asthma or not, and the diagnosis is made on a combination of the patient's symptoms and one or more breathing tests (e.g. spirometry), which look for airway narrowing. The problem is that, as asthma symptoms vary, the results may be normal by the time the tests are done. It is known from previous studies that patients find it very frustrating to have lots of tests, none of which provide a final answer, and that undiagnosed asthma can result in long-term lung damage.
This study will investigate how to detect asthma earlier, using new techniques and tests to see how they compare to current methods. It is important to identify asthma promptly so that treatment can be started, both to reduce symptoms and because, without treatment, patients can be at risk of serious asthma attacks.

Who can participate?
Patients aged 18 to 59 years who have symptoms that might be caused by asthma, including coughing, breathlessness, or wheezing and their GP would like further tests to look for potential asthma. Volunteer healthy controls will be invited to participate if they are aged 18 to 59 and do not have any current lung symptoms or suspicion of asthma or other chronic respiratory disease.

What does the study involve?
Patients who contact their GP with symptoms that suggest they might have undiagnosed asthma will be referred to the study. Patients will be included before they start any treatments, as this can affect the results. The study will include questionnaires about symptoms, a consultation with a research GP, in-person assessment including all the usual tests for asthma diagnosis, plus a panel of new tests, and a peak flow diary at home for two weeks, plus new home self-monitoring tests. Healthy volunteers (healthy cohort) with no symptoms will also complete the tests, as the comparison group.

The results in the suspected asthma cohort will be fed back to each participant's own GP for further treatment as needed. An expert panel will go through results to determine the diagnosis of either likely, unlikely or uncertain asthma based on the 'usual' test results. The test results will be compared between likely asthma and healthy cohorts, and new tests vs. usual tests, to see how accurate they are at picking up asthma. A survey and interview will be conducted with a selection of participants and clinicians about how they found the diagnostic tests and study processes.

What are the possible benefits and risks of participating?
There are no necessarily immediate benefits from participation in this study. It is hoped that this study will lead to those who have suspected asthma in the future being able to receive a clearer diagnosis, with less delay.

To work out why participants are experiencing symptoms, they will need to go through some or all of the standard of care tests listed above (approximately 1.5 hours of tests, potentially across several appointments/locations; plus, two-week home monitoring of peak flow), but they are also asked to complete some more tests, which will take more time. The additional time burden linked to the study is about 1-1.5 hours (including the time for the symptom questionnaires and telephone/video consultation) and using an additional test as part of the two-week home monitoring. There is no change to the ongoing treatment, which will be managed in the usual way by their GP practice.

The disadvantage of taking part in research as a healthy volunteer is the time burden. These are tests that they would not normally need to take.

Where is the study run from?
This study is being run from the Nuffield Department of Primary Care Health Sciences, University of Oxford.

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

Who is funding the study?
1. Asthma Lung UK
2. National Institute for Health and Care Research (NIHR) School for Primary Care Research.

Who is the main contact?
Dr Helen Ashdown, asthma-dx@phc.ox.ac.uk

Contact information

Type(s)
Scientific, Principal investigator

Contact name
Dr Helen Ashdown

ORCID ID
https://orcid.org/0000-0002-7758-7095

Contact details

Nuffield Department of Primary Care Health Sciences, Gibson Building, Radcliffe Observatory Quarter, Woodstock Road
Oxford
United Kingdom
OX2 6GG
-
helen.ashdown@phc.ox.ac.uk

Type(s)
Public

Contact name
Mrs Johanna Cook

ORCID ID
https://orcid.org/0000-0002-8750-8995

Contact details
Nuffield Department of Primary Care Health Sciences, Gibson Building, Radcliffe Observatory Quarter, Woodstock Road
Oxford
United Kingdom
OX2 6GG
-
Johanna.cook@phc.ox.ac.uk

Type(s)
Public

Contact name
Ms Zhanna Oganesova

ORCID ID
https://orcid.org/0009-0008-4754-8619

Contact details
Nuffield Department of Primary Care Health Sciences, Gibson Building, Radcliffe Observatory Quarter, Woodstock Road, ,
Oxford
United Kingdom
OX2 6GG
-
zhanna.oganesova@phc.ox.ac.uk

Additional identifiers

Integrated Research Application System (IRAS)
358432

Central Portfolio Management System (CPMS)

71898

Grant Code
NIHR SPCR-2021-2026 751

Study information

Scientific Title
Asthma-Dx: A platform for investigating novel diagnostic techniques to improve asthma diagnosis in primary care (pilot)

Acronym
Asthma-Dx

Study objectives
Primary
To conduct a mixed-methods evaluation (acceptability and feasibility) of the platform study design

Secondary (1) – SA Cohort Only
1) To assess the diagnostic accuracy* of new tests for asthma against standard-of-care diagnosis, alongside novel physiological tests

*Or diagnostic potential and informing further research, for earlier-stage tests

2) To assess the acceptability to patients of tests (both standard-of-care and novel tests) and the asthma diagnostic pathway

Secondary (2) – SA cohort Only
To assess the diagnostic accuracy of clinical history for asthma diagnosis

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 27/03/2026, London – Riverside Research Ethics Committee (2 Redman Place, Stratford, London, E20 1JQ, United Kingdom; -; riverside.rec@hra.nhs.uk), ref: 26/LO/0110

Primary study design
Observational

Secondary study design
Cohort study

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Asthma diagnosis in primary care

Interventions

Current methodology as of 11/05/2026:
Suspected asthma participants will present to their GP Surgery with symptoms suggestive of Asthma. If their GP thinks that they are potentially eligible to take part, they will be told about the study, given a PIS, and their HCP will seek consent to pass on details and health info to the research team by completing a referral form.

Healthy volunteers will be identified through advertisements about the study. They will be given a link to the PIS. They can register their interest in taking part in the study through an expression of interest form.

All participants will receive a telephone call from the trial team, who will take consent and confirm eligibility to take part and book them into their study visit appointment. They will also be sent a link to complete the baseline questionnaire.

For those who have suspected asthma, they will also have a call with a research GP who will record a full consultation with them about their symptoms and medical history.

All participants will then complete a face-to-face visit during which they will undergo all standard-of-care diagnostic tests for asthma and also any novel tests being looked at within the pilot, platform study. Details of these tests are listed as appendices to the protocol and PIS and if any are added or removed, an amendment will be submitted to update this. Primary analyses will assess each test individually against the reference standard. The results of the standard of care tests will be fed back to the GP of the suspected asthma cohort, so that their diagnosis may continue; we will not be involved in the clinical diagnosis of any participants. After this visit, the healthy volunteers involvement is complete.

The suspect asthma participants will complete two weeks of home monitoring using a peak flow machine, they will have a GP notes review completed and they will complete a user experience survey. A small group will also take part in the qualitative sub-study.

As part of the platform study evaluation, we will conduct qualitative interviews with HCPs who have been involved in recruiting at study sites, to understand their experiences and barriers /facilitators to recruitment, to inform potential continuation beyond a pilot.

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All participants will then complete a face-to-face visit during which they will undergo all standard-of-care diagnostic tests for asthma and also any novel tests being looked at within the pilot, platform study. Details of these tests are listed as appendices to the protocol and PIS and if any are added or removed, an amendment will be submitted to update this. Each test will be analysed individually against the standard of care tests; they will not be assessed against each other. The results of the standard of care tests will be fed back to the GP of the suspected asthma cohort, so that their diagnosis may continue; we will not be involved in the clinical diagnosis of any participants. After this visit, the healthy volunteers involvement is complete.

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Intervention Type
Other

Primary outcome(s)
1. Recruitment numbers over time measured using diversity metrics of those recruited, numbers referred versus recruited, and qualitative interviews with a subset of participants and HCPs at recruiting sites at one timepoint at the end of the recruitment period, with interviews within 3 months of recruitment

2. Diagnostic accuracy of individual tests against a clinical reference standard of likely diagnosis of asthma (composite reference standard using clinical features and standard-of-care test results by expert adjudication panel), defined as: a) Presence of asthma using diagnostic guidelines b) Diagnostic certainty of asthma measured using standard-of-care and novel tests at the diagnostic assessment visit (SA/HC cohorts), SA cohort: symptom questionnaires, structured clinical history, peak flow diary (two weeks)

Key secondary outcome(s))
1. Descriptive comparison of test results between cohorts: a) Likely diagnosis of asthma (Asth +) vs. healthy controls (HC) b) Unlikely diagnosis of asthma (Asth-) vs. HC measured using experience scores, survey, qualitative interviews with a subset of participants at the diagnostic assessment visit, electronic survey after study completion, qualitative interview within approximately three months of study completion

2. Research clinician's rating of the likelihood of asthma based on clinical history alone measured using index tests at the diagnostic assessment visit (SA/HC cohorts), SA cohort: symptom questionnaires, structured clinical history, peak flow diary (two weeks)

Completion date
31/12/2026

Eligibility

Key inclusion criteria

All:
1. Participant is willing and able to give informed consent for participation in the study
2. Aged 18 to 59 years

Suspected Asthma (SA) cohort:
1. Presenting to primary care with symptoms suggestive of asthma, e.g., breathlessness and/or wheeze and/or cough where the clinician would normally initiate further investigations for potential asthma

Healthy volunteers allowed
Yes

Age group
Adult

Lower age limit
18 years

Upper age limit
59 years

Sex
All

Total final enrolment
0

Key exclusion criteria
Current exclusion criteria as of 11/05/2026:
All:
1. Current or ex-smoker (including tobacco, cannabis and e-cigarettes). Having smoked less than 100 cigarettes in their lifetime can be included (as per CDC definition of a never-smoker), provided last smoking was at least a year ago.
2. Pre-existing or previously diagnosed chronic respiratory disease including asthma (resolved diagnoses or previous short-term treatments for asthma or other respiratory disease such as preschool wheeze labelled as asthma are eligible for inclusion)
3. Other current/recent medical condition which affects breathing or the immune system (hay fever/atopy can be included)
4. Current regular use of an inhaled steroid/long-acting bronchodilator or systemic immunosuppression (nasal steroids, or use of short-acting bronchodilators is allowed). Where possible, we will wait 6 weeks post-oral steroid course before diagnostic testing, as is recommended in clinical guidelines, unless there is a relevant clinical reason to do this sooner, as determined by the PI/usual GP.
5. Currently pregnant (this is due to the contra-indication to spirometry testing when pregnant, due to physiological changes and forced exhalations resulting from the reduced lung capacity, therefore we will not require formal pregnancy testing before participation)
6. Unstable/severe symptoms and/or any safety concerns which would make diagnostic assessment in a non-clinical research setting inappropriate for them or the research staff.

Healthy control cohort:
As above for ‘All’ and:

1. Current respiratory symptoms or suspicion of asthma or other chronic respiratory disease diagnosis
2. Childhood diagnosis of asthma or other chronic respiratory problems in childhood, including preschool wheeze

Previous exclusion criteria:
All:
1. Current or ex-smoker (including tobacco, cannabis and e-cigarettes). Having smoked less than 100 cigarettes in their lifetime can be included (as per CDC definition of a never-smoker), provided last smoking was at least a year ago.
2. Pre-existing or previously diagnosed chronic respiratory disease including asthma (resolved diagnoses or previous short-term treatments for asthma or other respiratory disease such as preschool wheeze labelled as asthma are eligible for inclusion)
3. Other current/recent medical condition which affects breathing or the immune system (hay fever/atopy can be included)
4. Current or recent (last 2 weeks) use of oral/long-acting inhaled bronchodilator or steroid or systemic immunosuppression (nasal steroids, or use of short-acting bronchodilators is allowed)
5. Currently pregnant (this is due to the contra-indication to spirometry testing when pregnant, due to physiological changes and forced exhalations resulting from the reduced lung capacity, therefore we will not require formal pregnancy testing before participation)
6. Unstable/severe symptoms and/or any safety concerns which would make diagnostic assessment in a non-clinical research setting inappropriate for them or the research staff.

Healthy control cohort:
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1. Current respiratory symptoms or suspicion of asthma or other chronic respiratory disease diagnosis
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Date of first enrolment
01/04/2026

Date of final enrolment
30/09/2026

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
-
-
-
England
-

Sponsor information

Organisation
University of Oxford

ROR
https://ror.org/052gg0110

Funder(s)

Funder type
Government

Funder Name
Asthma and Lung UK

Alternative Name(s)
asthmalunguk, Asthma + Lung UK, Asthma UK

Funding Body Type
Private sector organisation

Funding Body Subtype
Research institutes and centers

Location
United Kingdom

Funder Name
NIHR School for Primary Care Research

Alternative Name(s)
School for Primary Care Research, NIHR SPCR

Funding Body Type
Private sector organisation

Funding Body Subtype
Universities (academic only)

Location

United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are/will be available upon request from Dr Helen Ashdown, helen.ashdown@phc.ox.ac.uk, anonymised IPD data will be shared following publication of the final paper and the companies we are working with receiving their relevant data, data will be shared for ethically approved (if applicable) research projects for systematic review or similar types of analysis, via secure electronic data transfer.

IPD sharing plan summary

Available on request, Published as a supplement to the results publication