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Testing a home breath test to track asthma that gets worse around periods

Submission date 12/11/2026	**Recruitment status** Not yet recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [X] Record updated in last year
Registration date 18/11/2026	**Overall study status** Ongoing	
Last Edited 18/11/2026	**Condition category** Respiratory	

Plain English summary of protocol

Background and study aims
Many women with asthma find their symptoms get worse around their period. This is called perimenstrual asthma, and it is linked to more asthma attacks and hospital visits. There is no simple, objective way to measure it. Exhale-Dx is a small device that analyses the gases and natural chemicals in breath while a person breathes normally for a few minutes. This study aims to find out whether women can use Exhale-Dx at home, and whether their breath changes in a regular way across the menstrual cycle.

Who can participate?
Women aged 18 to 50 with asthma who still have natural periods, notice their asthma gets worse around their period, and are registered at South Molton Medical Centre in Devon.

What does the study involve?
After a visit at the practice to give consent and learn how to use the device, each woman breathes into Exhale-Dx at home every day or every other day for three months. She also keeps a short diary of her symptoms, peak flow and period in an app, and fills in short questionnaires about her asthma and quality of life. The study team phones her a few times, and she has a final visit at three months. Her usual asthma care continues as normal.

What are the possible benefits and risks of participating?
There is no direct benefit expected, but the study may help develop a better way to monitor this type of asthma. The breath test is non-invasive and uses a new single-use mouthpiece each time. The main burden is the time spent on daily tests and the diary.

Where is the study run from?
South Molton Medical Centre (UK), with Breath Predict Ltd (UK) as sponsor.

When is the study starting and how long is it expected to run for?
December 2026 to August 2027.

Who is funding the study?
Innovate UK (UK)

Who is the main contact?
Dr Victor Higgs, vhiggs@breathpredict.com

Contact information

Type(s)
Principal investigator, Scientific, Public

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Integrated Research Application System (IRAS)
379000

Study information

Scientific Title
A feasibility study of home-based longitudinal breath monitoring with Exhale-Dx to identify menstrual cycle linked respiratory signatures in premenopausal women with perimenstrual asthma in primary care

Study objectives
Primary objective
To find out whether Exhale-Dx, used at home, can detect repeatable changes in exhaled breath linked to menstrual cycle phase in women with perimenstrual asthma

Secondary objective
1. To assess the feasibility and acceptability of home breath monitoring (recruitment, retention, adherence, usability, technical performance)
2. Explore links between breath changes and symptoms, peak flow, asthma control and quality of life
3. Describe healthcare use
4. Inform a health economic analysis
5. Record safety and device problems

Ethics approval required
Ethics approval required

Ethics approval(s)

Not yet submitted

Primary study design
Interventional

Allocation
N/A: single arm study

Masking
Open (masking not used)

Control
Uncontrolled

Assignment
Single

Purpose
Device feasibility

Study type(s)

Health condition(s) or problem(s) studied
Perimenstrual asthma that worsens around menstruation

Interventions
Single-centre, single arm feasibility clinical investigation of a medical device. 30 women recruited through South Molton Medical Centre (England) in three groups of 10. After consent and training at the practice, each participant uses Exhale-Dx (a non-invasive breath analysis device measuring volatile organic compounds and carbon dioxide waveforms during normal breathing, with a single-use filter mouthpiece) at home daily or on alternate days for 3 months. Participants keep a daily symptom, peak flow and menstrual diary in the study app; complete the Asthma Control Questionnaire at baseline and monthly and the EQ-5D-5L at baseline and 3 months; and receive telephone check ins at week 1 and months 1 and 2. A final visit takes place at 3 months. Healthcare use and medicine changes are collected from GP records. Breath results are investigational and are not used to guide treatment; usual care continues unchanged.

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Exhale-Dx® breath analysis system

Primary outcome(s)
1. Menstrual cycle-linked change in breath profile measured using a prespecified Exhale-Dx breath score at the perimenstrual phase (3 days before to 3 days after menstruation starts) and mid-cycle

Key secondary outcome(s)

Completion date
31/08/2027

Eligibility

Key inclusion criteria
1. Female, aged 18 to 50 years
2. Doctor-diagnosed asthma recorded in the GP record, with at least one asthma medicine prescribed in the last 12 months
3. Pre-menopausal, with natural and reasonably regular menstrual cycles (21 to 35 days) over the last 3 months
4. Reports that asthma symptoms tend to worsen around menstruation
5. Registered with South Molton Medical Centre
6. Able and willing to use Exhale-Dx and the study app at home daily or on alternate days for 3 months and keep a symptom and menstrual diary
7. Able to give written informed consent

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Upper age limit
50 Years

Sex
Female

Total final enrolment
0

Key exclusion criteria
1. Pregnant, breastfeeding, or planning pregnancy during the study
2. Using hormonal contraception, HRT or other treatment that changes the natural menstrual cycle
3. Asthma attack needing oral steroids, A&E or hospital admission in the last 4 weeks
4. Other significant lung disease (e.g. COPD, bronchiectasis, cystic fibrosis, interstitial lung disease)
5. Current chest infection
6. Current smoker or regular vaper
7. Hysterectomy, endometrial ablation or other condition/treatment that stops or seriously disrupts periods
8. Taking part in another interventional study that could affect asthma or breath results
9. Lacks capacity to consent

10. Any other reason the study GP considers would make participation unsafe or results unreliable

Date of first enrolment
15/12/2026

Date of final enrolment
30/04/2027

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
South Molton Medical Centre
9-11 East Street
South Molton
England
EX36 3BZ

Sponsor information

Organisation
Breath Predict Ltd

Funder(s)

Funder type

Funder Name
Innovate UK

Alternative Name(s)
Technology Strategy Board

Funding Body Type
Government organisation

Funding Body Subtype

National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available