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# Using FeNO to optimally manage asthma

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| **Submission date**<br>12/03/2018 | **Recruitment status**<br>No longer recruiting | [X] Prospectively registered<br>[_] Protocol |
| **Registration date**<br>14/11/2019 | **Overall study status**<br>Completed | [_] Statistical analysis plan<br>[_] Results |
| **Last Edited**<br>07/02/2024 | **Condition category**<br>Respiratory | [_] Individual participant data<br>[_] Record updated in last year |

## Plain English summary of protocol

Background and study aims

The OPTIMAN study is designed to demonstrate how we can use a chemical that is measurable in the breath to better give treatments for asthma. Asthma is a huge problem in the United Kingdom, and it has been demonstrated that people who have asthma find it hard to know how much treatment to take. If they do not take the right amount of treatment, usually in the form of inhaled anti-inflammation medication, then they have an increased risk of symptoms and even possibly asthma attacks. By measuring the levels of nitric oxide (FeNO) in the breath we are able to adjust the doses of treatment and thus improve levels of control. The OPTIMAN study aims to do this for both those who have already been diagnosed and treated for asthma and for those who are coming to see their GP for the very first time with symptoms of asthma. We aim to get the diagnosis of asthma correct and then using FeNO optimise the drug treatment.

Who can participate?

This study will look at two groups of patients with asthma. Firstly, those who are already being treated with asthma and secondly those who are coming to their GP's for the very first time with symptoms of asthma. It will not be possible for those who are taking part in other studies to take part in OPTIMAN and we cannot accept those who are current smokers as this interferes with the recording of the FeNO.

What does the study involve?

The OPTIMAN study will be carried out at the local general practice centres by a team of highly trained expert nurses. When a suitable person, either with asthma or with the symptoms of asthma , has been identified, and they have agreed to take part in the study, they will book in to see the OPTIMAN nurse team. The team will measure their lung capacity (spirometry) as well as measure the level of exhaled nitric oxide (FeNO) in the participants breath. A medical history will be taken and a check on the ability to use inhaled medication will be performed, the participants will also complete a questionnaire which assesses how well controlled their asthma is. Following these measurements, the nurse and the GP will plan treatment for the participant. They will be seen again by the team one month after the initial visit and then again after 2 months. A final visit will occur at one year. The same measurements will be taken at each visit. We will check with the GP records to see how many times each participant has needed any help with control of their asthma, both locally and in hospital. We will be comparing how well controlled the asthma is in those who used the FeNO to guide treatment against those who did not.

What are the possible benefits and risks of participating?
We know that the use of FeNO to manage asthma leads to improved levels of control. It is hoped that those treated and entered into the OPTIMAN study will have better control of their asthma and the risk of a significant drop in their risk of an asthma attack will occur.
When performing the FeNO test a participant may have some cough and chest tightness. This is rare however if this occurs then the we will treat the person with medication that will open up the lungs.

Where is the study run from?
This study is being held in GP practices throughout the Thames Valley. The study is being carried out by nurses and doctors who are based at the Respiratory Unit at the Churchill Hospital and the lead researcher (RR) is based at the Nuffield Department of Medicine, within the University of Oxford.

When is the study starting and how long is it expected to run for?
This study will start at the beginning of December 2019. It will run for just over a year.

Who is funding the Study?
This study is being funded jointly by the British Lung Foundation and Circassia UK. Circassia are the company who manufacture the devices which measure the levels of FeNO in the breath.

Who is the main contact for OPTIMAN?
The main contact is Dr Richard Russell. He is leading the study and can be reached on his mobile phone 07899 743286. The lead nurse for OPTIMAN is Helen Jeffers and she can be reached by calling 01865 227456

# Contact information

### Type(s)
Public


### Contact name
Dr Richard Russell

### ORCID ID
http://orcid.org/0000-0002-3890-7201

### Contact details
Respiratory Medicine
Nuffield Dept of Medicine
Old Road Campus
Headington
Oxford
United Kingdom
OX3 7FZ


### Type(s)
Public


### Contact name
Mrs Emma Hedley

### Contact details
Oxford Respiratory Trials Unit (ORTU)
The University of Oxford
Oxford Centre for Respiratory Medicine
Churchill Hospital
Oxford
United Kingdom
OX3 7LE
+44 (0)1865 225205
emma.hedley@ndm.ox.ac.uk

## Additional identifiers

### EudraCT/CTIS number
Nil known

### IRAS number
211126

### ClinicalTrials.gov number
Nil known

### Secondary identifying numbers
CPMS 41626, IRAS 211126

## Study information

### Scientific Title
Optimising the management of asthma using FeNO to direct the use of inhaled steroids: the OPTIMAN study. A real-life implementation of biomarker (FeNO) based diagnosis and management of asthma in primary care

### Acronym
OPTIMAN

### Study objectives
That the use of FeNO to direct the use of inhaled steroids in both newly diagnosed and previously diagnosed asthma can improve patient outcomes.

### Ethics approval required
Ethics approval required

### Ethics approval(s)
Approved 19/02/2019, London-Surrey Ethics Committee (Whitefriars, Level 3, Block B, Lewins Mead, Bristol, BS1 2NT, United Kingdom; +44 (0)207104 8033; nrescommittee.secoast-surrey@nhs.net), ref: 19/LO/0221

### Study design
Cluster-controlled randomized trial

## Primary study design
Interventional

## Secondary study design
Cluster randomised trial

## Study setting(s)
GP practice

## Study type(s)
Diagnostic

## Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

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

## Interventions
This is a study of the use of exhaled nitric oxide (FeNO) to both diagnose asthma and improve the outcomes for patients with asthma. The intervention is simply adding measurement of FeNO to the standard care of patients with established or possible asthma. The use of FeNO will enable the clinicians (GP's) to make better treatment decisions. At their presentation to their GPs patients will have their FeNO measured. In control practices the result will not be utilised to affect management decisions by the clinician. In intervention practices the level of FeNO will be utilised to either prescribe inhaled corticosteroids or increase or decrease the dose of these key medications.

## Intervention Type
Other

## Primary outcome measure
Asthma control in the previous 2 weeks, assessed using the Asthma Control Test (ACT) at baseline, at 30 days and at 60 days and at 1 year.

## Secondary outcome measures
All outcomes are measured at first visit, 30 days, 60 days and 360 days:
1. Quality of life assessed by St. George's Respiratory Questionnaire (SGRQ)
2. Peak expiratory flow rate (PEFR) measured for 2 weeks, twice a day, after each visit; recorded on diary cards
3. Subject anxiety and depression measured using the Hospital Anxiety and Depression (HAD) questionnaire (self-administered) at each visit
4. Healthcare utilisation collected by the research team by taking a history from the patients and using primary care records
5. Changes to treatment (dose or drug) collected by the research staff from patient history as well as primary care records
6. Healthcare economic impact assessment performed using the data collected above by a

professional healthcare economist
7. The number of asthma attacks (exacerbations) collected through interview and GP records
8. Disease-related healthcare mastery measured using the Healthcare Mastery score

### Overall study start date
12/03/2018

### Completion date
31/08/2023

## Eligibility

### Key inclusion criteria
1. Participant is willing and able to give informed consent for participation in the study
2. Male or female, aged 18 years or above
3. Either (i) newly presenting with a possible diagnosis of asthma or (ii) having been previously diagnosed with asthma
and taking high dose inhaled corticosteroids
4. Able to use the NiOX FeNO monitoring equipment

### Participant type(s)
Patient

### Age group
Adult

### Lower age limit
18 Years

### Sex
Both

### Target number of participants
Planned Sample Size: 384; UK Sample Size: 384

### Total final enrolment
254

### Key exclusion criteria
1. Cannot give informed consent
2. Unable to obtain a satisfactory FeNO level recording
3. Severe life-threatening condition or one that would be anticipated to lead to death or disability within 1 year of study period
4. Current history of primary lung malignancy or current active pulmonary TB
5. Clinically relevant disease or disorder (past or present) which in the opinion of the investigator may either put the subject at risk because of participating in the study or may influence the results of the study or the subject's ability to participate in the study

### Date of first enrolment
14/12/2019

**Date of final enrolment**
01/08/2022

# Locations

**Countries of recruitment**
England

United Kingdom

**Study participating centre**
**University of Oxford**
Respiratory Medicine
Nuffield Dept. of Medicine
Old Road Campus
Oxford
United Kingdom
OX3 7FZ

# Sponsor information

**Organisation**
University of Oxford

**Sponsor details**
Joint Research Office
Block 60, Churchill Hospital
Old Road, Headington
Oxford
England
United Kingdom
OX3 7LE

**Sponsor type**
University/education

**Website**
http://ox.ac.uk

**ROR**
https://ror.org/052gg0110

# Funder(s)

### Funder type
Charity

### Funder Name
British Lung Foundation

### Alternative Name(s)
BLF

### Funding Body Type
Private sector organisation

### Funding Body Subtype
Trusts, charities, foundations (both public and private)

### Location
United Kingdom

## Results and Publications

### Publication and dissemination plan
For publication in peer-reviewed journal, dissemination through local healthcare population.

### Intention to publish date
30/09/2024

### 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 Richard Russell (richard.russell@ndm.ox.ac.uk) or Emma Hedley (Emma.Hedley@ouh.nhs.uk). This will be made available in the format of the electronic clinical research form (ECRF) that is being designed for this study. Data will be provided in a completely anonymised form and will be available for up to 5 years after the end of the study. Participant consent will be provided for this and the data will be made available from the end of the study. All data will be anonymised. The researchers will be using Microsoft Access and Excel for sorting and preliminary work. Full statistical analysis will be performed using SPSS.

### IPD sharing plan summary
Available on request

### Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|
| HRA research summary | | | 28/06/2023 | No | No |