

Using FeNO to optimally manage asthma

Submission date 12/03/2018	Recruitment status No longer recruiting	☒ Prospectively registered ☐ Protocol
Registration date 14/11/2019	Overall study status Completed	☐ Statistical analysis plan ☐ Results
Last Edited 07/02/2024	Condition category Respiratory	☐ Individual participant data ☐ 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 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

<https://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**Integrated Research Application System (IRAS)**

211126

Central Portfolio Management System (CPMS)

41626

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

Primary study design

Interventional

Study design

Cluster-controlled randomized trial

Study type(s)

Diagnostic

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(s)

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.

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Sex

All

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

United Kingdom

England

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

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

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