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COMET: Near-patient testing to guide COPD maintenance treatment in primary care

Submission date
30/01/2017

Recruitment status
No longer recruiting

Registration date
31/01/2017

Overall study status
Completed

Last Edited
02/04/2020

Condition category
Respiratory

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Chronic obstructive pulmonary disease (COPD) is a condition which affects the lungs and is often caused by smoking. It is characterised by breathlessness, cough and excess mucus production. COPD is commonly managed in primary care using inhaled medication, including inhaled corticosteroids (ICS). ICS treatment is recommended by NICE guidelines for worsening symptoms or moderate/severe COPD; however their use can be associated with side-effects such as pneumonia. Previous research suggests that patients with COPD vary in terms of markers (natural chemical indicators) of inflammation in their blood and breath, and this can affect disease outcomes. One of these markers is the blood eosinophil count (a type of white blood cell); another is a breath test called fraction of exhaled nitric oxide (FeNO) which measures airway inflammation. Further analysis of previous trials of ICS has found that broadly there is a greater response to ICS-containing medications in patients who have high blood eosinophil levels before treatment. The aim of this study is to gather preliminary information to look at whether blood and breath tests could be used to predict which patients would most benefit from ICS treatment, and it might be particularly useful to do this if results could be available immediately (near-patient testing).

Who can participate?
Adults aged 40 years and over who have COPD.

What does the study involve?
Participants are invited to attend an initial appointment in the research clinic at their GP surgery (approximately one hour) followed by three further visits (approximately 45 minutes) every two months over a total of six months (four appointments in total). At these appointments, they are asked questions about their COPD and medical history. They are also asked to complete some questionnaires about how good or bad their symptoms have been recently. A small clip is placed on the finger to measure oxygen levels, and height and weight are measured. Lung function tests (spirometry) are performed which test how well participants breathe in and out, both before and after using their reliever inhaler. Exhaled nitric oxide (FeNO) which is another breathing test, is also measured. Participants have a fingerprick blood test to measure the number and different types of white cells in the blood (eosinophils). A sample of blood is taken from a vein (a ‘normal’ blood test) – 3 small bottles (15ml of blood, or about 3 teaspoons) in total

each appointment. At the final appointment, participants are asked to complete a short questionnaire survey about their experience of having the tests above.

What are the possible benefits and risks of participating?
There are no direct benefits of taking part however it is hoped that this study will benefit patients with COPD in future by providing information about whether these tests can help guide whether steroid inhalers are beneficial for individual patients. This study is observational, which means that no treatments are being changed as part of the study, only additional tests. There are no anticipated serious risks from doing these tests. Taking blood samples may be uncomfortable and occasionally is associated with bruising or feeling faint. Breathing tests may require additional effort but should not be painful or uncomfortable. Testing will be done by a nurse or doctor trained in these procedures.

Where is the study run from?
Six primary care practices in the Oxfordshire area (UK)

When is the study starting and how long is it expected to run for?
January 2016 to December 2018

Who is funding the study?
National Institute for Health Research (UK)

Who is the main contact?
Dr Helen Ashdown
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Contact information

Type(s)
Public

Contact name
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Additional identifiers

Central Portfolio Management System (CPMS)

32551

Study information

Scientific Title
Near-patient testing to guide COPD MaintenancE Treatment in primary care (COMET): observational study to determine variability and accuracy of inflammatory biomarkers in stable state

Acronym
COMET

Study objectives
The aim of the study is to investigate how various markers and tests might be helpful in establishing which patients with COPD in primary care would most benefit from treatment with steroid inhalers, particularly looking at how these tests vary within and between patients, their feasibility, and how accurate near-patient tests are compared to laboratory tests.

Ethics approval required
Old ethics approval format

Ethics approval(s)
South East Scotland Research Ethics Committee 02, 18/08/2016, ref: 16/SS/0135

Study design
Observational; Design type: Cohort study

Primary study design
Observational

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Specialty: Primary Care, Primary sub-specialty: Respiratory disorders; UKCRC code/ Disease: Respiratory/ Chronic lower respiratory diseases

Interventions
Eligible participants will receive a letter from their GP inviting them to take part in the study, and return a reply form to the study team. They will have four appointments, at which details of their medical and COPD history will be taken, and measurements including respiratory questionnaires, height, weight, oxygen saturations, fraction of exhaled nitric oxide, spirometry and a venous blood sample for blood eosinophils, CRP and periostin, and a fingerprick sample for blood eosinophils. These four appointments will be two months apart over a six month follow-up period.

The same measurements above will be taken at each of the four appointments. At the fourth appointment, participants will be asked to complete a survey about the acceptability of the measurements and tests above.

Intervention Type
Other

Primary outcome(s)
Biomarker levels (eosinophils, FeNO, CRP, periostin) are measured at baseline, 2, 4 and 6 months

Key secondary outcome(s))
1. Diagnostic accuracy of near-patient eosinophils compared to laboratory eosinophils is assessed using fingerprick blood test at baseline, 2, 4 and 6 months
2. Feasibility of undertaking such measurements in a primary care setting is assessed using surveys created for the purpose of this study at 6 months

Completion date
31/12/2018

Eligibility

Key inclusion criteria
1. Participant is willing and able to give informed consent for participation in the study
2. Male or Female, aged 40 years or above
3. Have a diagnosis of COPD meeting spirometric criteria for diagnosis of COPD (FEV1/FVC ratio <0.7) as recorded in their primary care records

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Total final enrolment
96

Key exclusion criteria
1. Any previous diagnosis of bronchiectasis, cystic fibrosis, interstitial lung disease, lung cancer, alpha-1 anti-trypsin deficiency or other chronic respiratory disease not related to COPD or asthma
2. Co-existent active diagnosis of asthma (reviewed in the last 2 years)
3. Currently prescribed an ICS, or had a prescription for ICS in the last 2 years
4. Regularly takes oral steroids, or has been regularly taking oral steroids in the last 2 years. Regular use of oral steroids will in general be defined as a longer than 2 week course, although discrete short courses with tapering are acceptable for inclusion.
5. Prior inclusion in a clinical trial of an investigational medicinal product for airways disease in the last 90 days or which may involve administration of oral or inhaled steroid treatment

Date of first enrolment
01/01/2017

Date of final enrolment
31/07/2017

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
South Oxford Health Centre
Lake Street
Oxford
United Kingdom
OX1 4RP

Study participating centre
Gosford Hill Medical Centre
167 Oxford Road
Kidlington
United Kingdom
OX5 2NS

Study participating centre
Berinsfield Health Centre
Fane Drive
Berinsfield
United Kingdom
OX10 7NE

Study participating centre
Chipping Norton Health Centre
Russell Way
Chipping Norton
United Kingdom
OX7 5FA

Study participating centre
Donnington Medical Partnership
1 Henley Avenue
Oxford
United Kingdom
OX4 4DH

Study participating centre
Eynsham Medical Group
Conduit Lane
Eynsham
Witney
United Kingdom
OX29 4QB

Sponsor information

Organisation
University of Oxford

ROR
https://ror.org/052gg0110

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

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 helen.ashdown@phc.ox.ac.uk

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
Study website	Study website	11/11/2025	11/11/2025	No	Yes