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STudying Acute exaceRbations and Responses: COPD STARR Study. v1.0

Submission date
12/03/2015

Recruitment status
No longer recruiting

Registration date
20/08/2015

Overall study status
Completed

Last Edited
07/05/2021

Condition category
Other

[ ] 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 common chronic lung condition affecting many people over the age of 40. COPD means there is damage to the lungs which stops them from working properly. Some people with COPD have times when they get worse and need to see their doctor or specialist nurse. These episodes are known as lung attacks or exacerbations. The main treatment for these lung attacks are tablets in the form of steroids and antibiotics. Sometimes these treatments are helpful, but sometimes they do not work well. The treatments themselves are not without harm. We would like to understand the features or characteristics to determine which particular treatment will work in which particular patient, so that patients receive the right treatment at the right time.

Who can participate?
Patients aged 40 or over with COPD.

What does the study involve?
We will perform questionnaires, breathing tests and a pin-prick blood test when patients are well and also when they are unwell and having an exacerbation (lung attack) either at the GP surgery or when they are at home after a medical review with the emergency GP or the specialist respiratory nurse. We will then follow-up the patients' symptoms by telephone, conducting questionnaires on symptoms and recovery. We have previously studied and shown that we can identify different sub-groups of patients with different responses to steroids and antibiotics but we do not know if this is applicable to all patients with COPD. This information will help us to determine approaches to study further how to treat patients with COPD in the future.

What are the possible benefits and risks of participating?
There are no direct benefits to taking part in the study, but the information is vital to understanding how we can improve the care of our patients with COPD. There may be some mild discomfort in performing the breathing tests and the pin-prick blood test, but this discomfort will cease quickly.

Where is the study run from?
University of Oxford (UK).

When is the study starting and how long is it expected to run for?
April 2015 to September 2016.

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

Who is the main contact?
Dr Mona Bafadhel

Contact information

Type(s)
Scientific

Contact name
Dr Mona Bafadhel

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Additional identifiers

Protocol serial number
18557

Study information

Scientific Title
Studying the different characteristics of chronic obstructive pulmonary disease in primary care using near-patient testing and relating this to treatment responses during an acute exacerbation

Study objectives
Aims: To study the epidemiology of COPD exacerbation phenotypes using near-patient testing in a primary care practice and to derive rates of treatment failures (defined as re-treatment, hospitalisation or death within 30 days of initial consultation) within eosinophilic and non-eosinophilic exacerbations of COPD.

Objectives:
1. To perform an observational study in primary care to measure peripheral blood eosinophil counts in primary care practices at the onset of an exacerbation

2. To derive prevalence of eosinophilic and non-eosinophilic exacerbations of COPD
3. To quantify treatment failure rates and recovery in primary care in eosinophilic and non-eosinophilic COPD exacerbations using daily diary cards for symptoms and 30-day telephone consults and primary care records for assessment of treatment failures

More details can be found here: http://public.ukcrn.org.uk/Search/StudyDetail.aspx?StudyID=18557

Ethics approval required
Old ethics approval format

Ethics approval(s)
15SC0025; First MREC approval date 13/02/2015

Study design
Non-randomised; Observational; Design type: Cohort study

Primary study design
Observational

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Topic: Primary Care; Subtopic: Primary care; Disease: All Diseases

Interventions
Scheduled baseline visit 1
Demographic history: Participant demographics including age, smoking history and past COPD medical history will be collected.
Medication history: Full medication history will be collected, including the use of as required and over the counter medication. Any drug allergy will be documented and dates of flu vaccination, S. pneumoniae and H. influenzae B vaccinations will be recorded from medical records.
Past medical history: Full medical history will be collected from the participant and from the medical notes. The Charlson Comorbidity Index will be calculated.
COPD diagnosis history: The age of onset and age of diagnosis of COPD symptoms will be recorded from the participant and from the medical records.
Past exacerbation history: The frequency of exacerbations, including those requiring hospitalisation in the previous 12 months, will be captured from participant recollection and from the medical records. Medication prescribed at each exacerbation event (if available) from medical records will be captured.
Questionnaires: Patient reported outcome measures (PROs) will be sought to specifically test symptoms, health status, quality of life and any associated depression and anxiety. This will use the Medical Research Council dyspnoea scale; Visual analogue score; COPD Assessment Tool; the Hospital Anxiety and Depression Scale and the EuroQol 5D. Participants will be asked to complete a daily diary for assessment of symptoms and recovery following treatment. Instructions to use these questionnaires will be given to all participants. Each of these questionnaires are validated to be self-completed for ease of use.

Near patient testing:
Lung function: Spirometry will be performed to determine the forced expiratory volume in 1

second (FEV1) and the forced vital capacity (FVC) according to standard ATS/ERS criteria.
Airway Inflammation: Exhaled Nitric Oxide (FENO) will be used to determine airway inflammation. If the participant produces any sputum during these procedures, it will be collected into a sterile container and processed the same day for measurement of sputum cell differential counts and microbiology. If available after sputum processing, supernatants will be stored for cell mediator analysis. These samples will be used in a number of analytical ways not limited to but including cell isolation for functional assays, cell differential counts, and preparation of supernatants for mediator analysis.
Inflammatory phenotype: A blood test will be performed to determine the inflammatory phenotype for measurement of peripheral blood eosinophil counts and CRP levels.

Unscheduled exacerbation visit 2 (day 0)
Patients attending for an acute review of an exacerbation of COPD by their GP or community respiratory nursing team will be medically assessed and treated as per usual care with medication dispensed or prescribed as per standard guidelines. After this healthcare review, participants will be invited and seen by the research team. The participant will be invited to have data collected specifically related to:
1. Exacerbation history: symptom type, duration and severity assessed by direct questioning and symptom questionnaires
2. Near-patient testing: lung function, airway Inflammation and inflammatory phenotype
3. Recording of dispensed medication and duration.
The results of the near-patient testing will be recorded in the case record form (CRF) and not be used to guide any treatment change. A 30-day VAS will be issued (with self-addressed envelope to research centre) to participants. Guidance will be given on how to complete this. During an exacerbation the Anthonisen criteria with increased symptoms of breathlessness, sputum production and sputum purulence will be used.

Unscheduled exacerbation visit 3 (day 30)
Medical records will be reviewed to ascertain any history of a treatment failure (defined as the need for re-treatment, emergency attendances, hospitalisation or the event of death of any cause). All eligible participants will then be contacted via a telephone consultation for further review of treatment failure episodes (including the use of standby medication packs) and finally interviewed for completion of patient reported outcomes. All participants will be encouraged to post back their completed 30-day VAS diary at this telephone consultation.

Unscheduled exacerbation visit 4 (day 90)
A final medical record review of treatment failures and exacerbations will be recorded. This will be conducted via a further telephone interview to assess history of further exacerbations and for a final completion of patient reported outcomes.

Participants that have a further exacerbation within 30 days of the index exacerbation event will be categorised as a treatment failure episode and recorded as such. Participants that have an exacerbation between days 30 to 90 of the index exacerbation event will be invited to attend and have data captured as a new exacerbation event and the visit schedule is then restarted.

Follow Up Length: 18 month(s); Study Entry : Single Randomisation only

Intervention Type
Other

Primary outcome(s)

1. Measure the incidence of eosinophilic and non-eosinophilic COPD phenotypes in primary care. Using near-patient testing the blood eosinophil count and C reactive protein result will be used to quantify this at each stable assessment
2. Quantify the proportion of treatment responses and failures to standard/usual treatment for a COPD exacerbation in primary care. Treatment failure is defined as requiring further courses of treatment, medical review, hospitalisation or death within 30 days; subjects will be interviewed at 3 days to review the evidence for any treatment failure event. A treatment responder will be subjects that do not have a treatment failure

Key secondary outcome(s))
1. Measure patient-reported outcomes (symptoms, health status and healthcare utilisation) following treatment of an exacerbation of COPD. Quantified using the CAT, EuroQoL, MRC and VAS at day 30 and day 90 of an exacerbation
2. Derive pilot data quantifying treatment response following standard treatment of an exacerbation of COPD in primary for a future randomised clinical trial. Quantified at the end of the study period after the last subject has completed the follow-up data

Completion date
31/12/2017

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. Known diagnosis of COPD (either diagnosis made in primary or secondary care) as per national and international guidelines (NICE, 2010 & GOLD 2013), irrespective of severity
4. Current or ex-smoker
5. Smoking pack year history >10
6. Spirometry confirming fixed airflow obstruction (FEV1/FVC ratio <0.7)

Target Gender: Male & Female; Lower Age Limit 40 years

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
1. History of atopic childhood asthma
2. Current history of primary lung malignancy or current active pulmonary TB
3. Upon questioning the participant is HIV, hepatitis B or C positive

4. 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
5. Any clinically relevant lung disease other than COPD, considered by the investigator to be the primary diagnosis. For example mild to moderate bronchiectasis is acceptable in addition to COPD unless the bronchiectasis is considered to be the primary diagnosis
6. An alternative cause for the increase in symptoms of COPD that are unrelated to an exacerbation such as
6.1. Suspicion or clinical evidence of pneumonia
6.2. High probability and suspicion of pulmonary embolism
6.3. Suspicion or clinical evidence of a pneumothorax
6.4. Primary ischaemic event – ST or non ST elevation myocardial infarct and left ventricular failure (i.e., not an exacerbation of COPD)

Date of first enrolment
01/05/2015

Date of final enrolment
01/05/2016

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Respiratory Medicine Unit
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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 Mona Bafadhel at Mona.bafadhel@ndm.ox.ac.uk

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes