

Real world effects of medications for chronic obstructive pulmonary disease

Submission date 28/11/2016	Recruitment status No longer recruiting	☒ Prospectively registered ☒ Protocol
Registration date 05/12/2016	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 06/10/2022	Condition category Respiratory	☐ Individual participant data

Plain English summary of protocol

Background and study aims

Chronic Obstructive Pulmonary Disease (COPD) is a progressive lung disease, common in people who smoke. People with COPD have occasional disease flare ups requiring urgent treatment and in some cases hospitalisation. Medications used to treat people with COPD have been tested in randomised trials (studies where participants are randomly allocated to receive treatment or no treatment/dummy treatment), and the evidence obtained from these trials has been used to create treatment guidelines for people with COPD. Unfortunately, randomised trials have strict inclusion and exclusion rules, which means that many groups of people with COPD in the general community are not eligible and have not been studied, such as people aged over 80 years, people with lots of other illnesses as well as COPD and those with mild COPD disease. This means treatment decisions for these unstudied groups of patients are based on the assumption that information obtained in randomised trials applies to very different types of patients. It is not known whether this assumption is at all reasonable as the effects of medications often vary in different sorts of people. The aim of this study is to measure important effects of COPD treatments directly in patient groups not included in trials, to make better decisions about their treatments in future.

Who can participate?

Adults aged between 40 and 80 with COPD and adults over 80 years old, with other conditions, a history of lung surgery, or evidence of drug and alcohol abuse, and adults with mild COPD.

What does the study involve?

All participants receive their usual standard of care, driven by clinical need and consultation with their healthcare providers. Care is not influenced in any way by being included in this study. For three years after participants start receiving treatment from their healthcare providers, the researchers review medical records in order to monitor the progression of their COPD.

What are the possible benefits and risks of participating?

There are no direct benefits or risks involved with participating.

Where is the study run from?

London School of Hygiene & Tropical Medicine (UK)

When is the study starting and how long is it expected to run for?
November 2015 to February 2020

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

Who is the main contact?
Dr Ian Douglas
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Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
15/80/28

Study information

Scientific Title
The effects of medications for chronic obstructive pulmonary disease on mortality, pneumonia and exacerbation rate amongst UK patients with COPD

Study objectives
The aim of this study is to use electronic health records from general practice to see if they can be used to measure the treatment effects of COPD medications, validating our observations against the findings of a randomised trial.

Ethics approval required
Old ethics approval format

Ethics approval(s)

London School of Hygiene and Tropical Medicine Ethics Committee, 28/11/2016, ref: 11997

Primary study design

Observational

Study design

Multicentre observational cohort study

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Chronic obstructive pulmonary disease (COPD)

Interventions

Electronic patient medical records will be searched for prescriptions of study medication, as issued under routine clinical care. Based on these records patients will then be assigned to appropriate treatment groups, in order to estimate treatment effects. Records of respiratory function test results will also be searched to help ascertain whether people meet specific inclusion and exclusion criteria. Since the CPRD is a longitudinal database with people entering and leaving the database at different times, patients will be identified from the full spectrum of calendar time available (ranging from 1987 to 2016) though it is anticipated relatively few patients will be identified from earlier years as the database was smaller and records allowing us to ascertain the inclusion and exclusion criteria are less likely to be available.

Intervention Type

Drug

Phase

Not Applicable

Primary outcome(s)

1. COPD exacerbation rate will be determined using primary care electronic health records and linked hospital records, within three years of starting treatment
2. Mortality rate will be determined using primary care electronic health records and linked hospital records and linked office for national statistics mortality records, within three years of starting treatment
3. Pneumonia rate will be determined using primary care electronic health records and linked hospital records, within three years of starting treatment

Key secondary outcome(s)

Time to change in treatment for COPD will be determined using primary care electronic health records within three years of starting treatment

Completion date

29/02/2020

Eligibility

Key inclusion criteria

For the primary analysis, the following inclusion criteria will apply:

1. A diagnosis of COPD,
2. Age 40-80 years,
3. Lung function (FEV1<60% predicted, FEV1/FVC ratio <70%),
4. Smoking history

For the secondary analyses, the following inclusion criteria apply:

1. Age >80 years,
OR
2. History of lung surgery
OR
3. History of long term oxygen therapy
OR
4. Evidence of drug/alcohol abuse
OR
5. Substantial comorbidity

For the analysis of people with mild COPD, the following criteria will apply:

1. COPD diagnosis
2. >60% predicted FEV1 (or >50% plus MRC score 1 or 2, or >50% plus CAT score <10)
3. A maximum of 1 exacerbation in the year post COPD diagnosis

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

All

Key exclusion criteria

For the primary analysis closely mirroring the TORCH study, exclusions are:

1. History of asthma
2. History of lung surgery
3. Requirement for long-term oxygen therapy
4. Diagnosed alpha-1 antitrypsin deficiency
5. Evidence of drug/alcohol abuse

For the secondary analyses:

There are no exclusion criteria.

Date of first enrolment

01/05/2017

Date of final enrolment

01/08/2019

Locations

Countries of recruitment

United Kingdom

England

Study participating centre

London School of Hygiene & Tropical Medicine

Keppel Street

London

United Kingdom

WC1E 7HT

Sponsor information

Organisation

National Institute for Health Research

ROR

<https://ror.org/0187kwz08>

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

Results and Publications

Individual participant data (IPD) sharing plan

The data for this project will be obtained from the clinical practice research datalink and as such remain the property of the CPRD. Researchers may access the same data subject to CPRD procedures for access, please see www.cprd.com for more details.

IPD sharing plan summary

Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		25/03/2021	06/10/2022	Yes	No
Protocol article		25/03/2018	06/10/2022	Yes	No