ISRCTN73872958 https://doi.org/10.1186/ISRCTN73872958

Real world effects of medications for chronic obstructive pulmonary disease

Submission date
28/11/2016

Recruitment status
No longer recruiting

Registration date
05/12/2016

Overall study status
Completed

Last Edited
06/10/2022

Condition category
Respiratory

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Study design
Multicentre observational cohort study

Primary study design
Observational

Secondary study design
Cohort study

Study setting(s)
GP practice

Study type(s)
Treatment

Participant information sheet
No participant information sheet available

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 measure

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

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

Overall study start date
02/11/2015

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

Age group
Adult

Sex

Both

Target number of participants
As a minimum, the study team hopes to include 6,000 patients

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 anlayses:
There are no exclusion criteria.

Date of first enrolment
01/05/2017

Date of final enrolment
01/08/2019

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
London School of Hygiene & Tropical Medicine
Keppel Street
London
United Kingdom
WC1E 7HT

Sponsor information

Organisation
National Institute for Health Research

Sponsor details
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Sponsor type
Research council

Website
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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
United Kingdom

Results and Publications

Publication and dissemination plan
Planned publication of the findings of the study in three papers in high impact peer-reviewed journals by March 2021.

Intention to publish date
31/03/2021

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?
Protocol article		25/03/2018	06/10/2022	Yes	No
Results article		25/03/2021	06/10/2022	Yes	No