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Does ensuring people go home from hospital on the right inhalers after an exacerbation of chronic obstructive pulmonary disease reduce the risk of being re-admitted to hospital?

Submission date
01/09/2022

Recruitment status
No longer recruiting

Registration date
08/09/2022

Overall study status
Completed

Last Edited
19/07/2024

Condition category
Respiratory

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Chronic obstructive pulmonary disease (COPD) is the name for a group of lung conditions that cause breathing difficulties. This study tests if optimising the inhaled medicines of people living with COPD who have been admitted to hospital with a chest infection called an 'exacerbation', helps reduce the risk of death and readmission to hospital over the following 3 months. This is a preliminary study called a 'feasibility study' that will tell us if a full-size study to answer the question is possible.

Who can participate?
Patients aged 18 years and over who have been admitted to hospital with an exacerbation of COPD

What does the study involve?
Participants' clinicians will use a new tool to see if they are on the right inhalers. If not, they will suggest making a switch. Participants will then be phoned at 30 and 90 days to see how they got on with the new inhalers(s) if inhalers were switched, and to see if they were re-admitted to hospital. Some participants and some clinicians too will undergo more in-depth interviews about inhaler switching in this way.

What are the possible benefits and risks of participating?
The benefit to taking part is that there will be a closer look at the inhalers people are using. If there is a switch, the new inhaler(s) may not suit the person so well.

Where is the study run from?
The study is being run from the Royal Free Hospital in London, with people also invited to take part in Birmingham and Newcastle (all in the UK).

When is the study starting and how long is it expected to run for?
February 2022 to July 2023

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

Who is the main contact?
Ms Anne-Marie Preston, anne-marie.preston@nhs.net

Contact information

Type(s)
Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
309854

Protocol serial number
IRAS 309854, CPMS 52972

Study information

Scientific Title
Optimised inhalers to reduce chronic obstructive pulmonary disease exacerbation re-admissions and mortality: a feasibility study

Acronym
OPTIHALE

Study objectives
This study will test the hypothesis that re-admissions and mortality after a hospitalised chronic obstructive pulmonary disease (COPD) exacerbation can be reduced by optimising both inhaled drug prescription and device prior to discharge. This is a feasibility study.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 01/07/2022, Black Country Research Ethics Committee (The Old Chapel, Royal Standard Place, Nottingham HRA1 Meeting Room, NG1 6FS, UK; +44 (0)207 104 8010; blackcountry.rec@hra.nhs.uk), ref: 22/WM/0125

Study design
Feasibility study

Primary study design
Observational

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Exacerbations of chronic obstructive pulmonary disease (COPD)

Interventions
Participants' clinicians will use a new tool to see if they are on the right inhalers. If not, they will suggest making a switch. Participants will then be phoned at 30 and 90 days to see how they got on with the new inhalers(s) if inhalers were switched, and to see if they were re-admitted to hospital. Some participants and some clinicians too will undergo more in-depth interviews about inhaler switching in this way.

Intervention Type
Other

Primary outcome(s)
The primary aim of this study is to establish the feasibility of a future definitive trial; as such the feasibility outcomes are to measure:
1. The proportion of patients prescribed incorrect inhaled medicine, according to NICE guidance, assessed by review of the prescription chart and admission documentation prior to discharge
2. The proportion of patients with critical inhaler device errors, assessed by direct observation of technique prior to discharge
3. The proportion of patients with insufficient peak inspiratory flow rate for their current device, assessed using the In-Check device prior to discharge
4. The proportion of patients willing to have inhalers changed where a change is indicated, assessed by asking the patient prior to discharge
5. Of those eligible for an inhaler change, the proportion of patients in which the change is made and if not why not, by assessing the discharge prescription and interview with clinicians at the point of discharge
6. Of those who had an inhaler change, the continuation of that change in the community assessed by patient interview at 30 and 90 days
7. Patient perception of inhaled medication assessed using the Feeling of Satisfaction with Inhaler (FSI-10) questionnaire prior to discharge and at 30- and 90 days
8. Loss to follow-up at 30 and 90 days
9. Challenges in data collection assessed by interviews with clinicians using the tool throughout the study period
10. The time taken to collect the data and deliver the inhaler selection tool, assessed by timing use of the tool at the point of use
11. The first language distribution of patients with COPD at the three sites, to understand the need for translation of trial materials, assessed by interviews with patients prior to discharge

Key secondary outcome(s))
In addition, to inform the power calculation for a definitive study, the researchers will assess:
1. The mortality rate at 30 and 90 days, by review of electronic patient records
2. The all-cause re-admission rate at 30 and 90 days, by patient interview

3. The acceptability of the intervention is assessed using qualitative interviews. Then, based on input from trial participants and clinicians, the researchers will further refine and develop the inhaler selection tool. These interviews will be conducted after discharge.

Completion date
31/07/2023

Eligibility

Key inclusion criteria
1. In hospital with an exacerbation of COPD
2. Age 18 years or over
3. Able to provide informed consent

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
Discharge home with palliative care

Date of first enrolment
03/10/2022

Date of final enrolment
30/04/2023

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Royal Free Hospital
Pond Street
London
United Kingdom
NW3 2QG

Study participating centre

Queen Elizabeth Hospital
Edgbaston
Birmingham
United Kingdom
B15 2GW

Study participating centre
The Royal Victoria Infirmary
Queen Victoria Road
Newcastle upon Tyne
United Kingdom
TS1 4LP

Sponsor information

Organisation
Royal Free London NHS Foundation Trust

ROR
https://ror.org/04rtdp853

Funder(s)

Funder type
Government

Funder Name
National Institute for Health and Care 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 data-sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary

Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		04/03/2024	19/07/2024	Yes	No
HRA research summary			28/06/2023	No	No