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Chronic obstructive pulmonary disease (COPD) breathing record study

Submission date
18/05/2016

Recruitment status
No longer recruiting

Registration date
13/06/2016

Overall study status
Completed

Last Edited
10/05/2019

Condition category
Respiratory

[ ] 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 used to refer to a number of progressive devastating and debilitating lung diseases, which includes chronic bronchitis, emphysema and chronic obstructive airways disease. People that have COPD typically feel breathless after physical activity, have a persistent cough with phlegm and suffer frequently from chest infections. There is no cure for the condition, but making lifestyle changes (such as stopping smoking) and taking medications (inhalers and/or tablets) can alleviate symptoms. This study is being done to collect information that will be used in the development of a new medical device. The new device is intended to help people with chronic obstructive pulmonary disease (COPD) to monitor their condition at home on a daily basis. The device used in this study is called a capnometer. Different types of capnometer have been in use by doctors for many years. Capnometers measure the amount of carbon dioxide in the breath. The device that is used in this study is called the N-Tidal C. It is a small, battery-powered personal device to use indoors either at home, at work or in hospital.

Who can participate?
COPD patients aged at least 18

What does the study involve?
The study fits around the a COPD patient's normal treatment, tests and medication and there are no changes made to this treatment. At the start of the study each participant is trained in the use of the device and they are asked to use the device to record their normal relaxed breathing, 3 times a day (morning, afternoon and evening) every day for the next six weeks. A reading takes 75 seconds of ordinary breathing through the device. Participants who feel unwell, or have an infection, are asked to take more frequent breath records of up to six times a day if possible – that is twice in the morning, twice in the afternoon and twice in the evening - leaving at least an hour between readings. Standard care clinical assessments are taken at the start of the study, after 2 weeks, 4 weeks and, finally, 6 weeks. The tests for COPD include a check-up by the study doctor or nurse including the usual spirometry and blood gas tests. Each assessment visit takes between 15-20 minutes. Participants are also asked to complete a simple daily diary

of how their health and COPD changes and information on the use of the device. Finally, all participants receive a telephone call 2 weeks after their last assessment visit to check how they are and to ask if any of their medicines have changed.

What are the possible benefits and risks of participating?
Participants will not benefit directly from taking part in this study and the device used in the study does not provide any feedback to them. The information the researchers get from this study will help them to develop the device, and to learn more about the treatment and management of COPD. The study researchers do not believe that there are any risks to participants who use the N-Tidal C device in accordance with the instructions for use. An early version of it was tested on people with COPD and they did not report any side effects or difficulties with breathing through the device.

Where is the study run from?
Cambridge University Hospitals NHS Foundation Trust, Addenbrooke's Hospital, Lung Function Unit (UK)

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

Who is funding the study?
The Small Business Research Initiative for Healthcare (UK)

Who is the main contact?
Dr Ravi Mahadeva

Contact information

Type(s)
Public

Contact name
Dr Ravi Mahadeva

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number
NCT02814253

Secondary identifying numbers
19599

Study information

Scientific Title
An exploratory, observational clinical evaluation of the CRiL N--Tidal C data-collector capnometer to collect breathing records in patients with COPD

Acronym
CBRS

Study objectives
The purpose of this planned investigation is to collect data from patients whose COPD is undergoing change. Such patients are either at risk of an acute exacerbation of COPD, or they have already been hospitalised for treatment of an acute exacerbation. The intention is to correlate capnometric data during this journey with existing measurements (spirometry, blood gas, partial pressure of carbon dioxide [PaCO2], clinical symptoms and clinical assessments). It should then be possible to predict the exhaled CO2 signature of an exacerbation of COPD in normocapnic and hypercapnic patients.
The eventual aim of the N-Tidal C is to facilitate the monitoring and management of patients in the community with moderate to severe COPD. In its final developed form, the N-Tidal C will detect any changes in the patient's exhaled CO2 capnograph, which would indicate a worsening of their condition and risk of exacerbation. The device would then use a 'traffic light' warning system to advise the patient of a change of condition, prompting the patient to seek medical attention. This timely intervention in the community should reduce the number of COPD admissions to hospital.

Ethics approval required
Old ethics approval format

Ethics approval(s)
NRES Committee Yorkshire & The Humber - Bradford Leeds, 10/09/2015, ref: 15/YH/0369

Study design
Observational longitudinal study

Primary study design
Observational

Secondary study design
Longitudinal study

Study setting(s)
Hospital

Study type(s)
Other

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied
Specialty: Respiratory disorders, Primary sub-specialty: COPD

Interventions
Patients will be enrolled into one of two cohorts:

1. Stable patients with chronic hypercapnia (raised blood levels of CO2). They will be monitored in the community (community-based case managed group)
2. Hospitalised patients admitted with COPD related respiratory failure.
They will be monitored during recovery in hospital and post discharge (acute admission group)

Patients who give informed consent will be screened for the study. Patients in the case-managed group will be screened at home or in routine clinic visits. Patients in the acute admission group will be screened after admission to hospital as soon as they are well enough to understand the study and to give written informed consent.

The N-Tidal C data-collector capnometer will be explained to the patients and they will be trained how to use it. Case-managed patients will be asked to use the device at home over a period of approximately 6 weeks, 3 times per day (morning, afternoon and evening), or 6 times per day if they feel that they are starting an infection or an exacerbation. Hospitalised patients will also use the device 3 times per day as in-patients and will then continue with the monitoring after discharge from hospital for a total period of 6 weeks. All patients will complete a daily diary record.

Case-managed patients will undergo clinical assessment of COPD during screening at home or in the COPD clinic; in-patients will undergo clinical assessment of COPD following admission and before discharge from hospital. All patients will be assessed a further 3 times: during the second and fourth week in the community, and at the end of the 6-week assessment period. A brief follow-up review will be conducted approximately 8 weeks after the start of capnometer monitoring. At each assessment, capnometry measurements will be taken in addition to routine spirometry, and arterial (in-patients) or capillary (in the community) blood gasses. The trial will not interfere with routine management of the patient’s condition.

Intervention Type
Device

Primary outcome measure
Changes in exhaled CO2 profiles obtained by the N-Tidal C data-collector capnometer. The reading, which typically takes 60 seconds to collect, will be repeated three times daily, for a period of six weeks.

Secondary outcome measures
No secondary outcome measures

Overall study start date
07/01/2016

Completion date
01/07/2016

Eligibility

Key inclusion criteria
1. Patients of either sex, age 18 years and over, diagnosed with COPD, who have given written, informed consent
2. Patients in the case-managed group will have chronically elevated partial pressure of carbon dioxide (PaCO2) and will be susceptible to frequent exacerbations of COPD
3. Patients in the acute admission group will have been admitted to hospital via the emergency room for treatment of COPD-related ventilatory failure

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 30; UK Sample Size: 30

Key exclusion criteria
1. Diagnosis of neuromuscular disorders or kyphoscoliosis
2.
Patients who, in the opinion of the investigator are unlikely to comply with the requirements of the

use the device correctly, or keep the diary records

Date of first enrolment
17/02/2016

Date of final enrolment
05/05/2016

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Cambridge University Hospitals NHS Foundation Trust, Addenbrooke's Hospital
Lung Function Unit, Box 40
Cambridge Biomedical Campus
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CB2 0QQ

Sponsor information

Organisation
Cambridge Respiratory Innovations Ltd

Sponsor details
The Grange
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Cambridge
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CB24 4QG

Sponsor type
Industry

Website
http://criltd.co.uk

Funder(s)

Funder type
Government

Funder Name
The Small Business Research Initiative for Healthcare (SBRI Healthcare)

Results and Publications

Publication and dissemination plan

The first publication from the study will be a poster at the 2017 European Respiratory Society conference. Further publications are planned in high impact peer-reviewed journals.

Intention to publish date
01/08/2019

Individual participant data (IPD) sharing plan
The datasets generated and/or analysed during the current study are not expected to be made publicly available due to commercial sensitivity with the development of N-Tidal technology and personal respiratory monitors.

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Basic results		25/07/2017	01/08/2017	No	No
HRA research summary			28/06/2023	No	No