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Reducing the perioperative risk to patients suffering from COPD with pre-operative pulmonary rehabilitation

Submission date 31/08/2017	**Recruitment status** Stopped	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data [_] Record updated in last year
Registration date 19/09/2017	**Overall study status** Stopped	
Last Edited 11/12/2020	**Condition category** Respiratory	

Plain English summary of protocol

Background and study aims
COPD (chronic obstructive pulmonary disease) is a group of lung conditions that make it difficult to breathe due to narrowed airways. It is well known that people with COPD have more complications following surgery, and this study intends to test whether we can reduce that. It is also well known that pulmonary rehabilitation (a programme of exercise, education and support to help improve breathing) has very powerful effects upon breathlessness and quality of life in people with COPD, and reduces hospitalisations and deaths following exacerbations (flare ups) of COPD. Therefore it would be helpful to see if pulmonary rehabiliation can reduce complications following surgery. The aim of the study is to see whether it would be feasible to undertake a larger randomised control trial to assess whether offering pulmonary rehabilitation to participants prior to surgery will improve their recovery rate after surgery.

Who can participate?
Adults aged 18 and older who have COPD.

What does the study involve?
Participants who consented are randomly allocated to one of two groups. Those in the first group receive advice on smoking cessation, exercise and appropriate referral and education for those with newly diagnosed COPD. Those in the second group attending three sessions of pulmonary rehabilitation each week in the three weeks prior to their surgery, each session would last approximately two hours. In both groups participants are asked to complete questions and attend follow up visits.

What are the possible benefits and risks of participating?
Participants may benefit from reducing the post-operative pulmonary complications which allows them to return to normal every day activities more quickly. There are no risks to taking part in this study.

Where is the study run from?
This study is being run by the University of Oxford (UK) and takes place in John Radcliffe

Hospital (UK), Oxford Health NHS Trust – Pulmonary Rehabilitation (Continuing care site) (UK) and the Freeman Hospital (UK).

When is the study starting and how long is it expected to run for?
December 2016 to November 2019

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

Who is the main contact?
Mrs Emma Hedley
emma.hedley@ouh.nhs.uk

Contact information

Type(s)
Public

Contact name
Mrs Emma Hedley

Contact details
Oxford Respiratory Trials Unit
Churchill Hospital
Old Road
Headington
Oxford
United Kingdom
OX3 7LE
+44 1865 227456
emma.hedley@ouh.nhs.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
35051

Study information

Scientific Title
Reducing perioperative risk in chronic obstructive pulmonary disease with pre-operative pulmonary rehabilitation - A feasibility study

Study objectives

The aim of the study is to see whether providing a suitably tailored course of pulmonary rehabilitation, delivered prophylactically to surgical patients with COPD would reduce post-operative pulmonary complications and will facilitate patients returning to normal every day activities more quickly.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Yorkshire & The Humber - South Yorkshire Research Ethics Committee, 17/07/2017, ref: 17/YH/0220

Study design
Randomised; Interventional; Design type: Treatment, Psychological & Behavioural, Physical, Rehabilitation

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
See additional files

Health condition(s) or problem(s) studied
Perioperative Medicine and Pain Management

Interventions
Participants are randomised to either the control arm or the treatment arm.

Control Arm: Participants receive standard care which includes advice on smoking cessation, exercise and appropriate referral and education for those with newly diagnosed COPD.

Treatment Arm: Participant attends three sessions of pulmonary rehabilitation each week in the three weeks prior to their surgery, each session would last approximately two hours.

In both arms participants are asked to complete questions and attend follow up visits are per the schedule.

Intervention Type
Other

Primary outcome measure

As this is a feasibility study the primary outcomes are measured throughout the study include:
1. Recruitment rates
2. Demographics of recruited participants
3. Treatment compliance
4. Suitability of outcome data

Secondary outcome measures
Incidence of postoperative pulmonary complications for those participants receiving rehab v those that did not this is measured on day 7 following surgery.

Overall study start date
01/12/2016

Completion date
30/11/2019

Reason abandoned (if study stopped)
Participant recruitment issue

Eligibility

Key inclusion criteria
1. Adult patients, male and female aged 18 years or older with COPD
2. Has capacity to take part in this study
3. Scheduled for elective major (body cavity) surgery OR laparascopic surgery anticipated to last longer than two hours

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 72; UK Sample Size: 72

Total final enrolment
3

Key exclusion criteria
1. Inability to give informed consent
2. Insufficient command of English to understand the study documentation
3. Unable to participate in pulmonary rehabilitation treatment according to British Thoracic

Society guidelines
4. Patients scheduled cardiac, thoracic and orthopaedic surgery and orthopaedic surgery
5. If the participant attends a pulmonary rehab course as clinical management (as opposed to being part of the trial) then they would be excluded from the study

Date of first enrolment
16/10/2017

Date of final enrolment
06/03/2019

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
John Radcliffe Hospital
Headley Way
Headington
Oxford
United Kingdom
OX3 9DU

Study participating centre
Oxford Health NHS Trust – Pulmonary Rehabilitation (Continuing care site)
63 Blackbird Leys Road
Blackbird Leys
Oxford
United Kingdom
OX4 6HL

Study participating centre
Freeman Hospital
Freeman Road
High Heaton
Newcastle Upon Tyne
United Kingdom
NE7 7DN

Sponsor information

Organisation
University of Oxford

Sponsor details
Research Services
CTRG
Joint Research Office
Block 60
Churchill Hospital
Old Road
Headington
Oxford
England
United Kingdom
OX3 7LE

Sponsor type
Hospital/treatment centre

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

Publication and dissemination plan
Planned publication in a high-impact peer reviewed journal.

Intention to publish date
06/03/2020

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 please use this statement.

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?
Participant information sheet	version V1	07/06/2017	26/10/2017	No	Yes
Preprint results	non-peer-reviewed results in preprint server:	06/11/2019	07/11/2019	No	No
Results article	results	09/03/2020	11/12/2020	Yes	No
HRA research summary			28/06/2023	No	No