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

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

#### 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

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## 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