

Determining the optimal approach to identifying individuals with chronic obstructive pulmonary disease

Submission date 22/02/2011	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 31/03/2011	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 19/11/2018	Condition category Respiratory	<input type="checkbox"/> Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N/A

Study information

Scientific Title

Determining the optimal approach to identifying individuals with chronic obstructive pulmonary disease: a multi-centre randomised trial

Acronym

DOC study

Study objectives

1. To identify the most effective case-finding pathway for chronic obstructive pulmonary disease (COPD). The specific health service impacts across different possible pathways for undertaking COPD case finding amongst current smokers in primary care settings will be assessed.
2. To assess the cost-effectiveness of COPD case-finding pathways. A cost-per-true-positive-case-found analysis will be undertaken and health care resource use will be incorporated.
3. To evaluate the efficiency of the 'case finding' pathway. Key factors to consider will be the quality of the forced expiratory volume in one second (FEV1)/forced vital capacity (FVC), mechanical peak expiratory flow rate (PEFR) measurements and wheezometer measurements (in relation to the reference standard).
4. To evaluate whether undergoing the diagnostic test(s) has an impact on smoking behaviour to inform future smoking cessation studies.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Newcastle and North Tyneside 2 Research Ethics Committee, 29/07/2010, ref: 10/H0907/37

Study design

Multi-centre randomised trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

GP practice

Study type(s)

Treatment

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

Chronic obstructive pulmonary disease (COPD)

Interventions

1. Participants will undertake lung function tests (i.e. peak flow measurement, microspirometry and post-bronchodilator spirometry), a wheeze-detecting device (i.e. wheezometer) and a case-finding questionnaire
2. Further questionnaires will be completed during the study; a screening questionnaire and a follow-up questionnaire.

All participants receive the case-finding tests, with half randomised to receive the tests straight away and the remainder will receive the tests approximately 6 months later.

Intervention Type

Other

Phase

Not Applicable

Primary outcome measure

Effectiveness of diagnostic pathways - aim to identify the most effective pathway for use as the routine service model in primary care

Secondary outcome measures

1. Cost-effectiveness of COPD case-finding pathway
2. Efficiency of COPD case-finding pathway
3. Impact on smoking behaviour

Overall study start date

01/05/2011

Completion date

01/09/2013

Eligibility**Key inclusion criteria**

Current smokers aged 35 years or more who are registered with participating GP practices

Participant type(s)

Patient

Age group

Adult

Sex

Both

Target number of participants

600

Key exclusion criteria

1. Pregnancy
2. Recent history (within 8 weeks) of myocardial infarction, stroke, pulmonary embolism, chest /abdominal surgery or eye surgery
3. Any mental or physical condition (e.g. chest/abdominal pain/stress incontinence) or any other condition which means the participant is unable to undergo the case-finding tools

Date of first enrolment

01/05/2011

Date of final enrolment

31/07/2012

Locations**Countries of recruitment**

England

United Kingdom

Study participating centre

York Trials Unit

York

United Kingdom

YO10 5DD

Sponsor information**Organisation**

University of York (UK)

Sponsor details

c/o Sue Final

Innovation Centre

York

England

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Sponsor type

University/education

Website

<http://www.york.ac.uk/>

ROR

<https://ror.org/04m01e293>

Funder(s)

Funder type

Government

Funder Name

Department of Health (UK) - Respiratory Programme

Results and Publications

Publication and dissemination plan

The results are expected to be published in 2015

Intention to publish date

31/12/2015

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/06/2018		Yes	No