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Understanding how common persistent cough is in work-related lung disease

Submission date 25/08/2023	**Recruitment status** No longer recruiting	[ ] Prospectively registered [ ] Protocol
Registration date 04/12/2023	**Overall study status** Completed	[ ] Statistical analysis plan [ ] Results
Last Edited 04/12/2023	**Condition category** Respiratory	[ ] Individual participant data [ ] Record updated in last year

Plain English summary of protocol

Background and study aims
This is a questionnaire study aimed at identifying the presence and severity of cough in patients attending occupational lung clinics. Persistent coughing has been associated with many occupational and environmental substances (e.g. flour, dust), however the prevalence and severity of cough in this population is unknown. In order to understand the reasons for cough in these patients and develop effective therapies, it is important to first understand the scale of the problem.
Patients attending the occupational clinic as part of their routine care will be asked if they are interested in taking part in a questionnaire study, they will be given the patient information sheet and allowed time to read and ask questions.
Their written consent will be obtained prior to administration of the questionnaires. Following the collection of their demographics and questionnaire completion, the participant will have completed the study. Their notes will be checked at a later date to obtain their final respiratory diagnosis.

Who can participate?
Any patient with a work-related lung condition, who has had a persistent cough for greater than 8 weeks.

What does the study involve?
Questionnaires about their health and cough symptoms.

What are the possible benefits and risks of participating?
There are no risks to taking part, the study is simply a questionnaire with no sensitive information collected. There are no direct benefits to individuals taking part, however, this study may help us understand important symptoms and aid us to better treating patients in the future.

Where is the study run from?
Manchester University NHS Foundation Trust (UK)

When is the study starting and how long is it expected to run for?
March 2021 to April 2025

Who is funding the study?
North West Lung Charity (UK)

Who is the main contact?
Dr Huda Badri
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Contact information

Type(s)
Principal Investigator

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
258563

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
IRAS 258563

Study information

Scientific Title
Cough in Occupational Lung Disease

Acronym
COLD

Study objectives
Chronic cough is a troublesome condition that is defined by the presence of cough for >8 weeks. Neuronal dysfunction is now a recognised mechanism of refractory chronic cough. A wide variety of occupational lung conditions have recognised potential causes or exacerbating factors in persistent cough. Current guidelines now recommend screening employed patients for potential occupational and environmental causes of cough. However, the prevalence of persistent cough in the occupational lung disease population is unknown.

Chronic cough can be detrimental to the wellbeing of patients and there are no effective licensed therapies. Thus, early identification of patients with an occupational cause of persistent coughing is vital, as it can be necessary to alter their work environment or remove them from that workplace in order to treat them effectively.

Various studies have suggested that there are both direct and indirect mechanisms of occupational agents that can precipitate cough, e.g. stimulation of airway nerves and cough receptors by particulates such as construction dust, allergic inflammation from environmental allergens leading to inflammatory mediator release causing cough.

This research forms part of the initial exploratory work into potential neuronal mechanisms of occupation-induced cough and asthma. In order to develop studies to identify and investigate these mechanisms, we need to understand the patient demographics and identify the prevalence and severity of cough in this patient group.

Aim: To identify the prevalence of chronic cough in patients attending a specialist occupational lung clinic and to measure the effect of cough on their quality of life.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 10/05/2023, Cambridge South (Equinox House, City Link, Nottingham, NG2 4LA, United Kingdom; +44 207 104 8084; cambridgesouth.rec@hra.nhs.uk), ref: 23/EE/0088

Study design
Single centre observational study

Primary study design
Observational

Secondary study design
Cohort study

Study setting(s)
Hospital

Study type(s)
Other

Participant information sheet
See outputs table

Health condition(s) or problem(s) studied
Occupational lung diseases (airways and pneumoconiosis)

Interventions
Once consented, participant demographics and whether they report a chronic cough will be recorded and the participant will be asked to complete the Leicester Cough Questionnaire and a Visual Analogue Scale (VAS), which involved putting a mark on a 100-mm line to rate how severe their cough is. This is the end of the participant involvement, although their final diagnosis will be recorded once it is available in the participant's hospital records.

Intervention Type
Other

Primary outcome measure
The presence of a chronic cough at the clinic visit, as determined by asking the participant.

Secondary outcome measures
1. Leicester Cough Questionnaire score at the clinic visit.
2. Cough severity VAS score at the clinic visit.
3. Participant diagnosis, as determined by medical records following the clinic visit.
4. Participant demographics as recorded at the clinic visit.

Overall study start date
22/03/2021

Completion date
01/04/2025

Eligibility

Key inclusion criteria
1. Patients aged 18 years and over, up to the age of 80.
2. Suspected/ confirmed occupational lung disease
3. Able to read English to allow for completion of written questionnaires

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
80 Years

Sex
Both

Target number of participants
100

Key exclusion criteria
1. Patients currently receiving ACE inhibitors.
2. Patients presenting with a cough of ≤8 weeks duration.

Date of first enrolment
01/10/2023

Date of final enrolment
01/10/2024

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Manchester University NHS Foundation Trust
Cobbett House
Oxford Road
Manchester
United Kingdom
M13 9WL

Sponsor information

Organisation
Manchester University NHS Foundation Trust

Sponsor details
Research Office
1st Floor Nowgen Building
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lynne.webster@mft.nhs.uk

Sponsor type
Hospital/treatment centre

Website
https://mft.nhs.uk/

ROR
https://ror.org/00he80998

Funder(s)

Funder type
Charity

Funder Name
North West Lung Charity

Results and Publications

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

Intention to publish date
01/04/2026

Individual participant data (IPD) sharing plan
The current data sharing plans for this study are unknown and will be 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?
Participant information sheet	version 1.1	17/04/2023	01/11/2023	No	Yes