# The characterization and treatment of cough in lung cancer

Submission date	Recruitment status	<ul><li>Prospectively registered</li></ul>
25/10/2011	No longer recruiting	☐ Protocol
Registration date	Overall study status	Statistical analysis plan
23/01/2012	Completed	[X] Results
Last Edited	Condition category	Individual participant data
26/10/2022	Cancer	

# Plain English summary of protocol

https://www.cancerresearchuk.org/about-cancer/find-a-clinical-trial/a-study-find-out-more-about-coughing-people-with-lung-cancer-clic-study

# Contact information

# Type(s)

Scientific

#### Contact name

**Prof Alex Molassiotis** 

# Contact details

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# Additional identifiers

**EudraCT/CTIS** number

IRAS number

ClinicalTrials.gov number

# Secondary identifying numbers

11 DOG07 129

# Study information

#### Scientific Title

The Characterization and treatment of cough in Lung Cancer: a longitudinal survey

# Acronym

CLiC

# Study objectives

- 1. Cough is prevalent in patients with lung cancer. It can be subjectively and objectively measured over time using validated cough assessment tools that will be applicable to future trials assessing cough
- 2. Cough prevalence has a negative impact on the quality of life (QoL) of lung cancer patients and is influenced by factors due to the patient (such as continued smoking, co-morbid conditions, concurrent medications) and factors due to the tumour (location, stage, histology).

# Ethics approval required

Old ethics approval format

# Ethics approval(s)

NRES Committee NW - Greater Manchester South, 11 August 2011, ref: 11/NW/0374

# Study design

Prospective longitudinal observational cohort study

# Primary study design

Observational

# Secondary study design

Cohort study

# Study setting(s)

Hospital

# Study type(s)

Screening

# Participant information sheet

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

# Health condition(s) or problem(s) studied

Cough in Lung Cancer

#### **Interventions**

Day 0 Groups A and B: Case Report Form will be completed by investigator, Brief Reflux Inventory, Visual Analogue Scale (VAS), Manchester Cough in Lung Cancer Scale questionnaire

and Quality of LIfe (QOL) questionnaire. Spirometry will be performed on all patients. In Group B, the ambulatory cough monitor will be fitted.

Day 1 Group B: Ambulatory cough monitor removed.

Day 30 (+/- 7 days) Groups A and B: A telephone assessment to conduct the Manchester Cough in Lung Cancer Scale questionnaire and to instruct the patient to complete a VAS on the day at home. Patients will have been given a VAS on Day 0 to complete on day 30 at home. Case Report Form re: antitussives, opiates or angiotensin converting enzymes (ACE) inhibitors and current anticancer treatment will be completed by the study investigator.

Day 60 (+/ 7 days) Groups A and B: A VAS, Manchester Cough in Lung Cancer Scale questionnaire, investigator and QOL questionnaire will be completed. Case Report Form re: treatment data will be completed by the study investigator. Spirometry will be performed on all patients. A cough monitor will be refitted in group B.

Day 61 Group B: Ambulatory cough monitor removed.

This coincides with routine treatment appointments to minimise extra patient visits.

# **Intervention Type**

Other

#### **Phase**

Not Applicable

# Primary outcome measure

- 1. Frequency of cough, measured using 24-hour ambulatory cough monitoring at baseline and day 60 in a subset of patients
- 2. Severity of cough, measured using the Cough Severity Visual Analogue Scale at baseline, day 30 and day 60; the Cough Severity Diary at baseline and day 60; and the EORTC LC13 questionnaire at baseline and day 6060 and the Common Toxicity Criteria for Adverse Events v 4.0 at baseline and day 60

# Secondary outcome measures

- 1. Impact of cough on quality of life measured using the Manchester Cough in Lung Cancer Scale at baseline, day 30 and day 60
- 2. Clinical factors associated with cough severity and cough impact scores at baseline and day 60

# Overall study start date

05/10/2011

# Completion date

01/06/2012

# Eligibility

# Key inclusion criteria

- 1. Histologically or cytologically confirmed Non Small Cell Lung Cancer (NSCLC) or Small Cell Lung Cancer (SCLC)
- 2. WHO performance 0-2

3. Ability to give informed consent to participate

4. Age ≥18 years

# Participant type(s)

**Patient** 

# Age group

Adult

# Lower age limit

18 Years

# Sex

Both

# Target number of participants

180

# Total final enrolment

177

# Key exclusion criteria

Patients unable to complete self-reporting questionnaires

# Date of first enrolment

05/10/2011

# Date of final enrolment

01/06/2012

# Locations

# Countries of recruitment

England

**United Kingdom** 

# Study participating centre The Christie NHS Foundation Trust

Wimlsow Road Manchester United Kingdom M20 4BX

Study participating centre
University Hospitals of South Manchester NHS Trust
Southmoor Road

# Sponsor information

# Organisation

The Christie NHS Foundation Trust (UK)

# Sponsor details

c/o Ms Angela Ball
Research and Development Department
Wilmslow Road
Manchester
England
United Kingdom
M20 4BX
+44 (0)161 446 3000
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# Sponsor type

Hospital/treatment centre

# Website

http://www.christie.nhs.uk/

#### **ROR**

https://ror.org/03v9efr22

# Funder(s)

# Funder type

Government

# **Funder Name**

National Institute for Health Research (NIHR) (UK) (ref: DRF-2010-03-55)

# 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 of Characterisation of Cough in Lung Cancer to Thorax with results of trial and Further Evaluation of Manchester Cough in Lung Cancer Scale.

# 30/04/2018:

- 1. Results published in thesis 2015 https://www.research.manchester.ac.uk/portal/files/59982486/FULL\_TEXT.PDF
- 2. Results presented at British Thoracic Society Winter Meeting 2013 http://thorax.bmj.com/content/68/Suppl\_3/A101.2

# Intention to publish date

31/03/2017

# Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are/will be available upon request

# IPD sharing plan summary

Available on request

# **Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/01/2019	24/01/2019	Yes	No
Plain English results			26/10/2022	No	Yes