

The characterization and treatment of cough in lung cancer

Submission date 25/10/2011	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 23/01/2012	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 26/10/2022	Condition category Cancer	<input type="checkbox"/> Individual participant data

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

School of Nursing, Midwifery & Social Work
University of Manchester
Jean McFarlane Building
Room 5.310
Oxford Road
Manchester
United Kingdom
M13 9PL
+44 (0)161 306 7830
alex.molassiotis@polyu.edu.hk

Additional identifiers

Protocol serial number

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

Study type(s)

Screening

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(s)

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 60 and the Common Toxicity Criteria for Adverse Events v 4.0 at baseline and day 60

Key secondary outcome(s)

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

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 \geq 18 years

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

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**

United Kingdom

England

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

Manchester

United Kingdom

M23 9LT

Sponsor information**Organisation**

The Christie NHS Foundation Trust (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

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