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The characterization and treatment of cough in lung cancer

Submission date	Recruitment status	[_] Prospectively registered
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

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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

Manchester
United Kingdom
M23 9LT

Sponsor information

Organisation
The Christie NHS Foundation Trust (UK)

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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