ISRCTN14159936 https://doi.org/10.1186/ISRCTN14159936

Change in disability in activities of daily living over time among adults with advanced respiratory disease during the COVID-19 pandemic

Submission date
30/11/2020

Recruitment status
No longer recruiting

Registration date
14/12/2020

Overall study status
Completed

Last Edited
21/01/2025

Condition category
Respiratory

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
The researchers are very interested in finding out more about how people with advanced lung cancer or respiratory disease manage daily activities (e.g. washing, dressing, shopping, and walking) and how this changes over several months during the Coronavirus (COVID-19) pandemic. This is so they can identify when people with these conditions may become unable to manage everyday activities, what may cause them to have more difficulty (e.g. breathlessness) and what might help to improve their independence, in order to guide clinical practice and service provision.
This is important because people are living longer with advanced lung cancer or respiratory disease due to an ageing population and advances in treatment prolonging survival. This may change the illness trajectory of these conditions in terms of prolonging symptoms and disability. Disability in advanced disease has a specific effect on a persons' ability to perform daily activities, limiting a patients' independence and quality of life, impacting on care needs.

Who can participate?
Adults with a diagnosis of either advanced non-small cell lung cancer or respiratory disease (chronic obstructive lung disease (COPD) or interstitial lung disease (ILD))

What does the study involve?
This is an observational study of patients with advanced lung cancer or respiratory disease looking at how disability changes over time in daily activities (e.g. washing, dressing, shopping, walking) and associated factors including symptoms and social isolation. The researchers are recruiting from hospital and hospice in/outpatient settings throughout the UK and will be following participants for 6 months. Following consent, participants will complete a baseline questionnaire upon enrolment over the telephone and a series of monthly postal questionnaires over 6 months.

What are the possible benefits and risks of participating?
This research does not involve any changes to patient care, and so patients are unlikely to benefit personally from taking part, though participation may help to improve the care of others in future. The risks to taking part are very small, this research will not in any way affect the standard of clinical care participants might receive, care options, or any relationships they have with any staff or researchers. Some people may find some of the questions upsetting, but participants can choose not to answer questions if they do not want to and can withdraw at any time.

Where is the study run from?
Cicely Saunders Institute King's College London (UK)

When is the study starting and how long is it expected to run for?
January 2020 to August 2021

Who is funding the study?
National Institute for Health Research (NIHR) (UK)

Who is the main contact?
Lucy Fettes
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Contact information

Type(s)
Scientific

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Miss Lucy Fettes

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Type(s)
Public

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
271894

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
IRAS 271894

Study information

Scientific Title
Comparing disability in activities of daily living over time among adults with advanced lung cancer or respiratory disease during the COVID-19 pandemic

Acronym
DIScOVER

Study objectives
1. People with advanced lung cancer develop greater disability in activities of daily living over time than people with advanced respiratory disease
2. Symptom severity is positively associated with subsequent disability in activities of daily living
3. Use of an assistive device is positively associated with increased independence in activities of daily living
4. Social isolation is positively associated with increased dependence in activities of daily living

Ethics approval required
Old ethics approval format

Ethics approval(s)

Approved 11/02/2020, London - Camberwell St Giles Research Ethics Committee (Level 3, Block B, Whitefriars, Lewins Mead, Bristol, BS1 2NT, UK: +44 (0)207104 8204; nrescommittee.london-camberwellstgiles@nhs.net), REC ref: 19/LO/1950

Study design
Multi-center longitudinal prospective cohort study

Primary study design
Observational

Study type(s)
Other

Health condition(s) or problem(s) studied
Exploring disability in patients with non-small cell lung cancer or respiratory disease

Interventions
Sample: advanced no small cell cancer or respiratory disease
Recruitment sites: hospital lung cancer and respiratory inpatients and outpatient clinics; hospice /palliative care inpatients, outpatients, or community teams.
Outcome variable: disability in activities of daily living
Explanatory variables: symptom burden; assistive device use; social isolation
Outcome measures: Barthel Index; Lawton Brody IADL scale; WHO Disability Assessment Scale (WHODAS 2.0); Palliative Outcomes Scale-Symptoms; Chronic Disease Self-Efficacy Social Support Sub-scale
Data collection: Baseline self-reported questionnaire via telephone and monthly postal survey for 6 months or until death.

Intervention Type
Other

Primary outcome(s)
Disability (independence) in basic activities of daily living measured using the Barthel Index at baseline and monthly for 6 months

Key secondary outcome(s))
1. Disability (independence) in instrumental activities of daily living measured using the Lawton Brody IADL scale at baseline and monthly for 6 months
2. Disability severity in activities of daily living measured using the WHO Disability Assessment Scale (WHODAS 2.0) at baseline and monthly for 6 months
3. Symptom burden measured using the Palliative Outcomes Scale-Symptoms (POS-S) at baseline and monthly for 6 months
4. Confidence to receive social support measured using the Chronic Disease Self-Efficacy Social Support Sub-scale at baseline

Completion date
01/08/2021

Eligibility

Key inclusion criteria
1. Patients aged >18 years
2. Advanced lung cancer or respiratory disease as defined by one of the following:
2.1. Lung cancer: Inoperable stage III or IV non-small cell lung cancer
2.2. Chronic Obstructive Lung Disease (COPD): Severe or very severe stages of COPD according to the criteria set by the Global Initiative for Chronic Obstructive Lung Disease (GOLD): stage III (FEV1/FVC <70%. 30% ≤ FEV1 <50% predicted with or without chronic symptoms (cough, sputum production)) and stage IV (FEV1/FVC <70%. FEV1 <30% predicted plus chronic respiratory failure)
2.3. Interstitial lung disease (ILD): Carbon monoxide transfer factor (TLCO/DLCO) level of <40% or FVC <50% predicted
3. Patients with capacity to consent
4. Patients with ability to understand and complete a questionnaire in English
5. Life expectancy of >1 month as assessed by the person taking consent

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Total final enrolment
201

Key exclusion criteria
1. Patients aged <18 years
2. Patients who lack the capacity to consent
3. Patients who lack the ability to understand and complete a questionnaire in English
4. Life expectancy of <1 month as assessed by the person taking consent

Date of first enrolment
01/03/2020

Date of final enrolment
28/02/2021

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Princess Royal University Hospital (Kings College London NHS Trust)
Farmborough Common
Orpington
United Kingdom
BR6 8ND

Study participating centre
Nottingham University City Hospital
Hucknall Road
Nottingham
United Kingdom
NG5 1PB

Study participating centre
Macclesfield District General Hospital
Victoria Road
Macclesfield
United Kingdom
SK10 3BL

Study participating centre
South Tyneside District Hospital (South Tyneside and Sunderland NHS Foundation Trust)
Harton Lane
South Shields
United Kingdom
NE34 0PL

Study participating centre
Royal Cornwall Hospital
Treliske
Truro
United Kingdom
TR1 3LJ

Study participating centre

Medway NHs Foundation Trust
Windmill Road, Gillingham
Kent
United Kingdom
ME7 5NY

Study participating centre
St Christopher's Hospice
51-59 Lawrie Park Road
London
United Kingdom
SE26 6DZ

Study participating centre
St Michael's Hospice
25 Upper Maze Hill
Saint Leonards-on-sea
United Kingdom
TN38 0LB

Study participating centre
St Barnabas Hospice
Titnore Lane
Worthing
United Kingdom
BN12 6NZ

Study participating centre
Worthinh Hospital (Western Sussex NHS Foundation Trust)
Lyndhurst Road
Worthing
United Kingdom
BN11 2DH

Study participating centre
York Hospital
Wigginton Road
York
United Kingdom
YO13 8HE

Study participating centre
Guys and St Thomas' NHS Foundation Trust
Great Maze Pond
London
United Kingdom
SE1 9RT

Study participating centre
Asthma UK and British Lung Foundation Partnership
18 Mansell Street
London
United Kingdom
E1 8AA

Sponsor information

Organisation
King's College Hospital NHS Foundation Trust

ROR
https://ror.org/01n0k5m85

Organisation
King's College London

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research

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
Data will be archived in a secure unit at the Cicely Saunders Institute King's College London for 7 years, which is specified in the participant information sheet.

IPD sharing plan summary
Stored in repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		12/08/2021	04/01/2024	Yes	No
Results article		10/12/2023	21/01/2025	Yes	No
HRA research summary			28/06/2023	No	No
Participant information sheet	version V3.0	06/05/2020	04/01/2021	No	Yes
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Protocol file	version V2	06/05/2020	04/01/2021	No	No