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Exploring factors influencing patient outcomes in collapsed lung due to underlying lung disease

Submission date 10/01/2023	**Recruitment status** No longer recruiting	[_] Prospectively registered [X] Protocol
Registration date 20/03/2023	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 22/04/2024	**Condition category** Respiratory	[_] Individual participant data [_] Record updated in last year

Plain English summary of protocol

Background and study aims

Secondary spontaneous pneumothorax (SSP) is a medical emergency where an abnormal collection of air develops in the space between the lung and the chest wall, causing lung collapse. This occurs in patients with existing lung diseases such as chronic obstructive pulmonary disease (COPD). In the UK, patients with SSP are usually treated by inserting a drain into the chest to remove the air. The drain is stitched in place and left until the air is completely removed. The drain typically remains in place for over a week, leading to long hospital stays. Sometimes these patients need surgery to help stop the air leaking into the lung, but it is also recognised that these patients may not be fit for major surgery. Unfortunately, we don't have data from UK patients about the key consequences of developing a secondary spontaneous pneumothorax. For example, we don't know how long patients stay in hospital, how many go for surgery, and how many develop complications. With this information we can better plan for care, but also look at why some patients stay longer in hospital and why some patients need surgery, whilst others don't. The aim of this study is to gather information about SSP in an attempt to answer some of these unknown questions. We will recruit patients admitted to hospital with SSP throughout the UK over a period of 1 year. We will collect routine data from the patient's records, such as age, medical history and how long they stay in the hospital.

Who can participate?

Any patient with a collapsed lung with known or suspected underlying lung disease OR who is over the age of 50 with a significant smoking history is eligible to participate in this study. Patients with a collapsed lung because of an injury or a medical intervention are not eligible.

What does the study involve?

This is an observational study, which means that nothing additional is required from participants outside of their routine care. They will be informed about the study and given the option to decline to participate. The study team will collect data on the patients' background, their medical history, whether they are or have been a smoker, how fit the patient is and data related to their collapsed lung and how it is managed. Further data will then be collected at 1 month and 6 months post-enrolment. There are no additional interventions required.

What are the possible benefits and risks of participating?
There are no direct clinical benefits to participants from engaging in this research as it is observational. Once the results are published, we hope that the knowledge obtained will benefit patients in the future by helping clinicians understand better how to manage patients with this condition, taking into account different factors that may influence their outcomes. The observational nature of this study means that there are no additional risks to patients from participating.

Where is the study run from?
The lead site is North Bristol NHS Trust (UK)

When is the study starting and how long is it expected to run for?
May 2022 to September 2024

Who is funding the study?
Rocket Medical Plc (UK)

Who is the main contact?
Dr Eleanor Barton, eleanor.barton@nbt.nhs.uk (UK)

Study website
https://inspirerespiratory.co.uk/studies/lisp/

Contact information

Type(s)
Scientific

Contact name
Dr Eleanor Barton

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
316472

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
CPMS 53700, IRAS 316472

Study information

Scientific Title
Longitudinal investigation of secondary pneumothorax

Acronym
LISP

Study objectives
To determine the characteristics, healthcare burden, management and outcomes of patients with secondary spontaneous pneumothorax in the UK.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 01/12/2022, South West – Frenchay Research Ethics Committee (Ground Floor, Temple Quay House, 2 The Square, Bristol, BS1 6PN, UK; +44 (0)207 104 8106; frenchay.rec@hra.nhs.uk), ref: 22/SW/0125

Study design
Multicentre prospective longitudinal cohort study

Primary study design
Observational

Secondary study design
Cohort study

Study setting(s)
Hospital

Study type(s)
Treatment

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
Secondary spontaneous pneumothorax

Interventions
Patients presenting with secondary spontaneous pneumothorax (SSP) to any of the hospitals involved in the study will be screened and invited to participate in the study by trained clinicians or research nurses. SSP is defined in this study as a spontaneous pneumothorax with no history of trauma or iatrogenic intervention preceding it in a patient with known or suspected lung disease or a patient over the age of 50 with a smoking history. Patients with SSP will almost exclusively require admission under a specialist respiratory team, and as such we anticipate high patient identification rates.

We will collect data on the patient's demographics, past medical history and history of current illness, smoking status including cannabis, asbestos and other inhalational exposures, clinical frailty score (CFS) and performance status (PS). We will also collect data related to the pneumothorax and its management (e.g. digital or analogue assessment of air leak, size of the pneumothorax on CXR, procedures performed and their outcomes).
Further data will be collected from the patient's medical records at 1 month and 6 months post enrolment, to encompass the patient's length of stay, number and type of interventions, recurrence, and mortality. These two-time points allow for the collection of complete data sets, acknowledging that some patients may have a prolonged stay exceeding 1 month and ensuring that enough time has elapsed to capture the incidence of recurrence.

Intervention Type
Other

Primary outcome measure
1. Patient demographics: age (years), gender (M/F), socioeconomic status (Index of multiple deprivations) measured from the patient's medical records at baseline
2. Number and type of procedures required (number, procedures performed) measured from the patient's medical records at baseline, 1 month and 6 months
3. Outcomes: Length of stay (days), air leak duration (days), mortality (death rate) measured from the patient's medical records at baseline, 1 month and 6 months

Secondary outcome measures
There are no secondary outcome measures

Overall study start date
13/05/2022

Completion date
30/09/2024

Eligibility

Key inclusion criteria
1. Emergency attendance to hospital with secondary spontaneous pneumothorax (SSP), confirmed by radiology, with SSP defined as spontaneous pneumothorax in presence of known or suspected lung disease OR spontaneous pneumothorax
2. Aged ≥50 years old
3. History of smoking

Participant type(s)

Patient

Age group
Mixed

Lower age limit
16 Years

Upper age limit
50 Years

Sex
Both

Target number of participants
Planned Sample Size: 120; UK Sample Size: 120

Total final enrolment
213

Key exclusion criteria
1. Aged <16 years old
2. Latrogenic pneumothorax
3. Traumatic pneumothorax

Date of first enrolment
15/02/2023

Date of final enrolment
31/03/2024

Locations

Countries of recruitment
England

United Kingdom

Wales

Study participating centre
Southmead Hospital
Southmead Road
Westbury-on-trym
Bristol
United Kingdom
BS10 5NB

Study participating centre
Maidstone Hospital
Hermitage Lane
Maidstone
United Kingdom
ME16 9QQ

Study participating centre
Worthing Hospital
Lyndhurst Road
Worthing
United Kingdom
BN11 2DH

Study participating centre
Royal Devon University Healthcare NHS Foundation Trust
Royal Devon University NHS Ft
Barrack Road
Exeter
United Kingdom
EX2 5DW

Study participating centre
Northern General Hospital
Herries Road
Sheffield
United Kingdom
S5 7AU

Study participating centre
John Radcliffe Hospital
Headley Way
Headington
Oxford
United Kingdom
OX3 9DU

Study participating centre
Dewi Sant Hospital
Albert Road

Pontypridd
United Kingdom
CF37 1LB

Study participating centre
Torbay Hospital
Newton Road
Torquay
United Kingdom
TQ2 7AA

Study participating centre
St Thomas' Hospital
Westminster Bridge Road
London
United Kingdom
SE1 7EH

Study participating centre
Freeman Hospital
Freeman Road
High Heaton
Newcastle upon Tyne
United Kingdom
NE7 7DN

Study participating centre
Derriford Hospital
Derriford Road
Crownhill
Plymouth
United Kingdom
PL6 8DH

Study participating centre
Yeovil District Hospital
Higher Kingston
Yeovil
United Kingdom
BA21 4AT

Study participating centre
Queen Elizabeth Hospital
Mindelsohn Way
Edgbaston
Birmingham
United Kingdom
B15 2TH

Study participating centre
Worcestershire Royal Hospital
Charles Hastings Way
Worcester
United Kingdom
WR5 1DD

Study participating centre
Aneurin Bevan University Lhb
Headquarters - St Cadoc's Hospital
Lodge Road
Caerleon
Newport
United Kingdom
NP18 3XQ

Study participating centre
North Tyneside General Hospital
Rake Lane
North Shields
United Kingdom
NE29 8NH

Study participating centre
Arrow Park Hospital
Arrowe Park Road
Wirral
United Kingdom
CH49 5PE

Study participating centre

Harrogate District Hospital
Lancaster Park Road
Harrogate
United Kingdom
HG2 7SX

Study participating centre
University Hospitals of North Midlands NHS Trust
Newcastle Road
Stoke-on-trent
United Kingdom
ST4 6QG

Study participating centre
Norfolk and Norwich University Hospital
Colney Lane
Colney
Norwich
United Kingdom
NR4 7UY

Sponsor information

Organisation
North Bristol NHS Trust

Sponsor details
Research and Innovation
Floor 3, Learning and Research Centre
Bristol
England
United Kingdom
BS10 5NB
+44 (0)117 4149330
helen.lewis-white@nbt.nhs.uk

Sponsor type
Hospital/treatment centre

Website
http://www.nbt.nhs.uk/

ROR

https://ror.org/036x6gt55

Funder(s)

Funder type
Government

Funder Name
National Institute for Health and Care 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

Funder Name
Rocket Medical Plc

Results and Publications

Publication and dissemination plan
1. Planned publication in a high-impact and peer-reviewed journal
2. Presentation at conferences
3. Information will be accessible via the Academic Respiratory Unit and INSPIRE webpage

Intention to publish date
28/02/2025

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are not expected to be made available as patients did not consent to this level of data sharing.

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file	version 1.2	21/12/2022	14/01/2023	No	No
HRA research summary			28/06/2023	No	No