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Improving our understanding of factors influencing patient outcomes in pleural disease

Submission date
10/01/2023

Recruitment status
Recruiting

Registration date
20/03/2023

Overall study status
Ongoing

Last Edited
06/11/2024

Condition category
Respiratory

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
The pleural membranes are two thin layers of tissue covering the outside of the lungs, which are vulnerable to different diseases including, pleural effusions, where excess fluid accumulates in the space between the lung and the chest wall (the pleural space); pneumothorax, where the pleural space fills with air causing the lung to collapse; pleural cancer (mesothelioma), this is usually associated with asbestos exposure; and, pleural thickening, where the lining around the lung becomes scarred, often because it has been inflamed in the past. All of these conditions can cause breathlessness, which can be severe. Unfortunately, a general lack of research means there are many unanswered questions regarding how best to diagnose and manage pleural diseases. There is often no single test that can provide us with a diagnosis, and patients frequently need multiple procedures to diagnose their condition and manage symptoms. We plan to create a new, long-term study to collect data on patients with pleural disease, to improve our understanding of how to diagnose and manage their condition, and the impact their disease and its management have on their quality of life.

Who can participate?
Any patient presenting to North Bristol's tertiary pleural service with confirmed effusion, pneumothorax or pleural thickening, who is over the age of 16 and lives within reach of the service

What does the study involve?
The team will invite every patient who attends Southmead hospital with a pleural condition to take part in a simple follow-up study. Data will be recorded about participants' health, and store small amounts of routinely collected blood, fluid and tissue for future laboratory tests. These samples will be used to apply more cutting-edge tests as they become available, which may improve the ability to diagnose the underlying cause of pleural disease. This study does not require any additional visits to the hospital in addition to routine care. Patients will also be asked to fill out brief questionnaires at enrolment, 4 months and 12 months after enrolling about how they are affected by their condition.

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, it is hoped 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 the 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, Southmead Hospital (UK)

When is the study starting and how long is it expected to run for?
June 2021 to March 2029

Who is funding the study?
1. Rocket Medical Plc (UK)
2. Southmead Hospital Charity (UK)
3. National Institute for Health and Care Research (NIHR) (UK)

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

https://www.cancerresearchuk.org/about-cancer/find-a-clinical-trial/a-study-looking-at-new-ways-to-diagnose-and-monitor-people-with-diseases-of-the-lung-lining

Contact information

Type(s)
Scientific

Contact name
Dr Eleanor Barton

ORCID ID
http://orcid.org/0000-0003-0381-810X

Contact details
Pleural Clinical Research Fellow
Academic Respiratory Unit
North Bristol NHS Trust
Southmead Hospital
Bristol
United Kingdom
BS10 5NB
+44 (0)117 414 8033
eleanor.barton@nbt.nhs.uk

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
319757

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
CPMS 54190, IRAS 319757

Study information

Scientific Title
Severn Pleural Disease Outcomes: Long Term Insights Study

Acronym
SPOTLight

Study objectives
The aim of this long-term observational study is to improve our understanding of the long-term, patient-reported outcomes of pleural disease.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 24/02/2023, Wales REC 6 (Public Health Wales, Building 1, Jobswell Road, St David's Park, SA31 3HB, UK; +44 1267 61 1164; Wales.REC6@wales.nhs.uu), ref: 23/WA/0018

Study design
Single-centre longitudinal prospective observational 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
Respiratory

Interventions
Patients presenting with radiologically confirmed pleural disease including (but not limited to) pneumothorax, pleural effusion, pleural thickening or pleural cancer (mesothelioma) to North Bristol NHS Trust will be screened and invited to participate by a member of the study team. The team 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). The team will also collect data related to their condition and its management, for example, radiological and thoracic ultrasound appearances, the number and type of interventions undertaken and digital measurements of air leaks in the case of pneumothorax. For patients with pleural effusions, if blood or pleural fluid samples are collected as part of their routine care, additional research samples will also be collected for use in current or future studies. For patients who undergo a pleural biopsy procedure following enrolment, additional tissue samples may be obtained and retained for research purposes if felt appropriate by the operator. These data and sample collections are not study-specific procedures but are performed as part of the participants' routine clinical care.
At enrolment and 4- and 12-months post-enrolment, patients will be asked to complete 2 routine questionnaires to provide patient-reported outcome measures. These are study-specific, not part of the patient's routine care. Where necessary, additional PROMS relevant to a specific sub-study the patient may be eligible for may also be collected during the baseline assessment. These will be undertaken at the initial assessment, and either remotely, or during the routine clinical review at 4 and 12 months.
Further data will be collected from the patient's medical records at 4 months and 12 months post enrolment, to encompass the patient's length of stay, number and type of interventions, and mortality. These two timepoints allow for the collection of complete data sets, acknowledging that some patients may have a prolonged diagnostic pathway or require recurrent procedures to manage their symptoms. A final diagnosis will be recorded after 12 months, based on the diagnosis of their treating clinician, and ratified by a second pleural specialist.

Intervention Type
Other

Primary outcome measure
1. Breathlessness and pain measured using the patient-reported outcome measures (PROMs) Visual Analogue Scale (VAS) at baseline, 4 months and 12 months
2. Health-related quality of life measured using the EuroQol 5D Health Questionnaire (EQ-5D-5L) at baseline, 4 months and 12 months

Secondary outcome measures
There are no secondary outcome measures

Overall study start date
30/06/2021

Completion date
01/03/2029

Eligibility

Key inclusion criteria

1. Confirmed presence (radiologically) of either:
1.1. Pleural effusion/pleural thickening OR
1.2. Spontaneous primary or secondary pneumothorax
2. Patient normally lives within the catchment area of the Bristol hospitals and is unlikely to relocate within 12 months
3. Aged 16 years old and over
4. Has access to telephone and/or internet

Participant type(s)
Patient

Age group
Adult

Lower age limit
16 Years

Sex
Both

Target number of participants
Planned Sample Size: 1000; UK Sample Size: 1000

Key exclusion criteria
To be eligible to participate in the cohort, none of the following criteria should apply:
1. Previously enrolled in SPOTLight
2. Patient (or appropriate proxy) is not able to provide written informed consent
3. Patient is in the final stages of life or sufficiently frail to make study involvement inappropriate

Date of first enrolment
02/05/2023

Date of final enrolment
02/05/2028

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Southmead Hospital
Southmead Road
Westbury-on-trym

Bristol
United Kingdom
BS10 5NB

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)1174149330
Researchsponsor@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

Funder Name
North Bristol NHS Trust

Alternative Name(s)
NBT

Funding Body Type
Government organisation

Funding Body Subtype
Local government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
1. Planned publication in a high-impact and peer-reviewed journal
2. A specific dissemination plan will be devised for each individual question as it is studied and a full report prepared upon completion of the study
3. Presentation of study results at conferences
4. Study results will be accessible via the Academic Respiratory Unit webpage

Intention to publish date
01/03/2030

Individual participant data (IPD) sharing plan
The data sharing plans for the current study are unknown and will be made available at a later date

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
	version 1.0				

Protocol file	16/11/2022	16/01/2023	No	No
HRA research summary		26/07/2023	No	No