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An observational study to better understand the outcomes in patients with pleural effusion due to lung cancer

Submission date 08/10/2024	**Recruitment status** Recruiting	[X] Prospectively registered [ ] Protocol [ ] Statistical analysis plan [ ] Results [ ] Individual participant data [X] Record updated in last year
Registration date 23/10/2024	**Overall study status** Ongoing	
Last Edited 18/10/2024	**Condition category** Cancer	

Plain English summary of protocol

Background and study aims

The lungs are covered by two thin layers, called the pleura, which are vulnerable to many different diseases. If cancer spreads to the pleura, it can cause irritation and a build-up of fluid around the lung (a malignant pleural effusion). Patients affected by an effusion can experience breathlessness and lower quality of life, but there is a lot of variability between people. For example, some people produce fluid much more quickly than others and others respond better to treatment than others. At present, we can't predict which patients will do better and which ones will do worse over time. The main aim of this study is to gather information about what happens to patients and about how these effusions evolve. Eventually, improving our knowledge in this area might help doctors better advise patients on what might happen to them and which treatments to choose.

Who can participate?

The study will focus on patients with a specific kind of lung cancer (lung adenocarcinoma) who have developed a pleural effusion. The study will be restricted to adults without any other kind of cancer, who are also able to complete the necessary follow-up visits.

What does the study involve?

If willing to participate, eligible patients will first be asked to provide us with basic details about their medical history and to have samples of blood and pleural fluid taken. We will also ask for detailed information about quality of life using special questionnaires. At the same visit, patients may also be asked to have a chest X-ray, CT scan and a thoracic ultrasound, to help us understand what is happening inside the chest. An important part of the study is analysing the pleural fluid for changes to DNA, and people will be asked to provide permission for this specifically.

Patients will then be asked to return to the study site for a further two visits to repeat the above tests, first after 3 months and then after another 3 months. After these two visits, patients will exit the study and the research team will analyse their samples and information to help answer the important study questions.

What are the possible benefits and risks of participating?
There are unlikely to be any direct benefits for patients participating in the study, however, the information obtained will hopefully allow doctors and scientists to develop new tests and treatments for people like them in the future. Some of the study tests (such as fluid drainage) carry a very small risk of harm, but this will be discussed before every procedure. In theory, the extra chest x-rays and CT scans in the study will lead to some additional radiation exposure, but this is unlikely to cause any harm and is actually similar to what often happens as part of normal patient care. The study will be approved by an ethics committee in the UK before starting, and all tests will be performed by people who are experts.

Where is the study run from?
Southmead Hospital (UK)

When is the study starting and how long is it expected to run for?
January 2024 to December 2027

Who is funding the study?
The study has been funded by the UK Medical Research Council, with additional support from Rocket Medical UK.

Who is the main contact?
1. Elisabeth North, elisabeth.north2@nbt.nhs.uk
2. Dr Rahul Bhatnagar, rahul.bhatnagar@bristol.ac.uk

Contact information

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Scientific, Principal Investigator

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Additional identifiers

EudraCT/CTIS number

IRAS number
340605

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
MR/X030938/1, NBT 5539, IRAS 340605

Study information

Scientific Title
Outcome prediction tests in lung cancer-associated pleural effusion

Acronym
OPTICAL

Study objectives
This observational study looks to gather detailed information regarding the clinical and biochemical changes occurring to patients who are suffering with malignant pleural effusions caused by lung cancer.

Ethics approval required
Ethics approval required

Ethics approval(s)
Not yet submitted

Study design
Observational longitudinal cohort study

Primary study design
Observational

Secondary study design
Longitudinal study

Study setting(s)
Hospital

Study type(s)
Other

Participant information sheet
No participant information sheet available

Health condition(s) or problem(s) studied
Lung adenocarcinoma with malignant pleural effusion

Interventions
Patients to undergo study assessments at baseline, 3 months, and 6 months post enrolment. Each assessment to include: blood and pleural fluid sampling, thoracic ultrasound, chest radiograph, quality of life questionnaires, and clinical assessment for key outcomes.

Intervention Type
Other

Primary outcome measure
Survival at 6 months measured using patient records

Secondary outcome measures
1. Response to individualised anticancer therapy is measured using CT at 3 months and 6 months post enrolment
2. Development of pleurodesis is measured using ultrasound and fluid output at 3 months and 6 months post enrolment
3. Development of pleural fluid septation is measured using ultrasound at 3 months and 6 months post enrolment
4. Radiological tumour progression is measured using CT at 3 months and 6 months post enrolment

Overall study start date
01/01/2024

Completion date
31/12/2027

Eligibility

Key inclusion criteria
1. Malignant pleural effusion due to lung adenocarcinoma, defined as either:
1.1. An effusion with cytological or histological evidence of lung adenocarcinoma in fluid or pleural tissue; or
1.2. Histologically or cytologically proven lung adenocarcinoma and a pleural effusion with no other demonstrated cause
2. Pleural collection which is either:
2.1. Amenable to safe ultrasound-guided thoracentesis; or
2.2. Treated with a functioning indwelling pleural catheter (IPC)

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
110 Years

Sex
Both

Target number of participants
100

Key exclusion criteria
1. Age <18 years
2. Patient is not able to provide informed consent to study participation
3. Patient is not willing to attend study follow-up visits
4. Patient has no access to a telephone or other method of remote communication
5. Patient is likely to relocate out of region within 6 months of enrolment
6. Active malignancy other than lung adenocarcinoma
7. Evidence of pleural infection (as determined by the treating clinician)
8. Patient is in the final stages of their life (as determined by the treating clinician)
9. Uncorrectable bleeding diathesis (for patients who would need thoracentesis)
10. Previously enrolled in the OPTICAL study

Date of first enrolment
01/01/2025

Date of final enrolment
01/10/2026

Locations

Countries of recruitment
England

Scotland

United Kingdom

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

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

Study participating centre
Queen Elizabeth University Hospital
1345 Govan Road
Glasgow
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G51 4TF

Study participating centre
Sheffield Teaching Hospitals NHS Foundation Trust
Northern General Hospital
Herries Road
Sheffield
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S5 7AU

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

Study participating centre
Wythenshawe Hospital
Southmoor Road
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Sponsor information

Organisation
North Bristol NHS Trust

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Southmead Hospital
Bristol
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BS10 5NB
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Sponsor type
Hospital/treatment centre

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

ROR
https://ror.org/036x6gt55

Funder(s)

Funder type
Government

Funder Name
UK Research and Innovation

Alternative Name(s)
UKRI

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Funder Name
Rocket Medical

Results and Publications

Publication and dissemination plan
Publication in a peer-reviewed journal will take place following study completion and analysis

Intention to publish date
01/01/2028

Individual participant data (IPD) sharing plan
Upon publication of the study data, the datasets generated during and/or analysed during the current study will be stored in a publicly available repository (University of Bristol Research Data Repository [data.bris]).

IPD sharing plan summary
Stored in publicly available repository, Available on request