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Predicting how quickly fluid around the lung will come back after draining

Submission date 19/07/2021	**Recruitment status** No longer recruiting	[X] Prospectively registered [X] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [X] Record updated in last year
Registration date 29/09/2021	**Overall study status** Completed	
Last Edited 10/01/2025	**Condition category** Cancer	

Plain English summary of protocol
https://www.cancerresearchuk.org/about-cancer/find-a-clinical-trial/a-study-to-try-and-work-out-when-fluid-around-the-lungs-comes-back-repeat

Background and study aims
People with incurable cancer commonly feel breathless due to the build-up of fluid around the lung. Treatment aims to help symptoms and prevent admission to hospital. This is done by draining fluid off, but it often comes back. When this happens, patients are offered a permanent implanted drain so they can drain the fluid off regularly at home. However, sometimes the fluid builds up very quickly before there is time to implant a drain. The patient becomes very breathless and needs an emergency hospital admission. In other people, the fluid builds up slowly and they may never need another drain. The aim of this study is to improve treatment by finding a way to predict how quickly fluid will come back.

Who can participate?
Patients aged 18 years and over who have a pleural effusion and are coming to the Pleural Clinic to have the fluid drained off

What does the study involve?
Participants will be asked some extra questions about their symptoms before they have the fluid drained and complete a questionnaire about their quality of life. They may also have some extra blood tests and pleural fluid samples taken. These extra samples are optional and participants can still take part even if they do not wish to have these extra samples taken. About 10 ml (about 2 teaspoonfuls) of blood and 10 ml of pleural fluid will be collected at the first visit. These samples will be taken at the same time as the standard clinical samples. Participants will have an ultrasound after the fluid has been drained. This ultrasound is additional to standard care. Participants will be asked to complete a short daily diary about their breathing over 1 week. To complete this diary, they will be asked to mark on a single horizontal line of 10 cm how breathless they are feeling on the day. This should not take more than a few minutes each day. When participants come back to Pleural Clinic for the results of their fluid analysis 1 week after the drainage procedure, they will have a chest X-ray at this appointment and further drainage if necessary. This is part of standard medical care that they would have whether they wish to be part of this study or not. At this visit, participants will be asked to complete a short

questionnaire. This questionnaire consists of statements relating to mobility, self-care, usual activities, pain/discomfort and anxiety and depression. They can either complete the questionnaire on paper or they can have the questions read to them and the researcher will record the participant's responses. Participants will not have to come to the hospital any extra times to be part of the study but they will be contacted at 1 month and 3 months after their procedure to find out if they have needed any further pleural procedures or other treatments, or if they have had any emergency hospital attendances. They will also be asked to complete the questionnaire again over the phone at 3 months.

What are the possible benefits and risks of participating?
There are no specific disadvantages or risks of taking part in this study. All chest X-rays, clinic visits and most procedures would happen regardless of whether participants are part of the study or not. However, the participants will have an additional thoracic ultrasound and they will be asked to donate samples of their blood and pleural fluid, complete the daily breathlessness diary and complete a questionnaire, which will require some extra time on their part.

Where is the study run from?
Norfolk and Norwich University Hospitals NHS Foundation Trust (UK)

When is the study starting and how long is it expected to run for?
June 2021 to September 2023

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

Who is the main contact?
Dr Eleanor Mishra
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

Integrated Research Application System (IRAS)
295614

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
CPMS 49373, IRAS 295614

Study information

Scientific Title
Reaccumulation rate of Pleural Effusions After Therapeutic aspiration: an observational cohort study to determine baseline factors associated with the rate of pleural fluid reaccumulation following therapeutic aspiration in patients with malignant pleural effusion attending a pleural clinic

Acronym
REPEAT phases 1 and 2

Study objectives
It is hypothesized that there are baseline clinical variables that determine how quickly pleural fluid will reaccumulate after therapeutic aspiration. Determination of these variables will allow us to develop a clinical score to predict this and improve patient management.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 15/06/2021, London - Queen Square Research Ethics Committee (HRA NRES Centre Bristol, 3rd Floor, Block B, Whitefriars, Lewins Mead, Bristol, BS1 2NT, UK; +44 (0)207 104 8061; queensquare.rec@hra.nhs.uk), REC ref: 21/PR/0607

Study design
Observational; Design type: Cohort study

Primary study design
Observational

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Malignant pleural effusion

Interventions
Screening:
1. Identification of patients attending Pleural Clinic for therapeutic aspiration

2. Contact participants via telephone to let them know about the study and provide them with a patient information leaflet in the post with their clinic appointment

Day 0:
1. When patients attend the Pleural Clinic, they will have the opportunity to discuss the study and have their questions answered. They will then give informed consent for enrolment into the study
2. Patients will have bloods taken as part of routine clinical care. An additional optional sample will be taken for the study
3. Patients will have a thoracic ultrasound performed as part of routine clinical care
4. Patients will then undergo therapeutic aspiration and samples of the pleural fluid that would otherwise be discarded will be stored
5. Patients will then have a repeat thoracic ultrasound. This is not part of standard clinical care
6. Patients will have a chest X-ray as part of standard clinical care
7. They will be provided with a breathlessness diary for them to record their breathlessness daily for 1 week

Day 7:
1. The patient will attend clinic as part of their routine clinical care
2. They will have a chest X-ray as part of standard clinical care
3. The diary will be collected
4. The patient will have a thoracic ultrasound as part of standard clinical care

Definitive pleural procedure:
This will occur when indicated clinically. Patients will have a chest X-ray and ultrasound as part of standard clinical care and undergo a definitive pleural procedure (thoracoscopy, chest drain insertion or indwelling pleural catheter insertion)

Day 30:
Follow up by telephone/review of hospital records to determine further pleural procedures, emergency hospital attendances

3 months:
Follow up by telephone/review of hospital records to determine further pleural procedures, emergency hospital attendances

Intervention Type
Procedure/Surgery

Primary outcome(s)
The size of pleural effusion measured using chest X-ray on day 0 and day 7

Key secondary outcome(s))
Biomarkers measured at baseline:
1. Patient biomarkers (e.g. duration of symptoms in days) measured using questionnaires
2. Effusion biomarkers (e.g. volume of fluid drained) measured using data recorded during the drainage procedure
3. Pleural fluid biomarkers (e.g. total protein) measured using standard laboratory analysis
4. Serum biomarkers (e.g. CRP) measured using standard laboratory analysis

Completion date

26/09/2023

Eligibility

Key inclusion criteria
1. Participant is willing and able to give informed consent for participation in the study
2. Aged 18 years or above
3. Diagnosed with pleural effusion on CT or ultrasound (US)
4. Patient attending for therapeutic aspiration (large volume drainage) of their pleural effusion: there is no specific minimal pleural fluid volume but this should be larger than required for diagnosis alone (typically 60 ml is taken for diagnostic purposes)
5. Known or suspected malignancy as the underlying cause of the effusion
6. In the Investigator's opinion, is able and willing to comply with all study requirements

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Total final enrolment
241

Key exclusion criteria
1. Patients who are pregnant or lactating
2. Pleural infection or other condition requiring admission and chest drain insertion
3. Known transudative pleural effusion or pleural effusion thought to be primarily due to cardiac, renal or hepatic impairment

Date of first enrolment
11/10/2021

Date of final enrolment
26/06/2023

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Norfolk and Norwich University Hospital
Norfolk and Norwich University Hospitals NHS Foundation Trust
Colney Lane
Colney
Norwich
United Kingdom
NR4 7UY

Study participating centre
John Radcliffe Hospital
Oxford University Hospitals NHS Foundation Trust
Headley Way
Headington
Oxford
United Kingdom
OX3 9DU

Study participating centre
Southmead Hospital
North Bristol NHS Trust
Southmead Rd
Bristol
United Kingdom
BS10 5NB

Study participating centre
Derriford Hospital
University Hospitals Plymouth NHS Trust
Derriford Road
Derriford
Plymouth
United Kingdom
PL6 8DH

Study participating centre
Leicester Royal Infirmary
University Hospitals of Leicester NHS Trust
Infirmary Square

Leicester
United Kingdom
LE1 5WW

Sponsor information

Organisation
Norfolk and Norwich University Hospitals NHS Foundation Trust

ROR
https://ror.org/01wspv808

Funder(s)

Funder type
Government

Funder Name
NIHR Central Commissioning Facility (CCF); Grant Codes: NIHR201466

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be stored in a publicly available repository

IPD sharing plan summary
Stored in publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No
Participant information sheet	version v2.0	27/05/2021	22/07/2021	No	Yes
Participant information sheet	version v2.0	27/05/2021	22/07/2021	No	Yes
Participant information sheet	version v2.0	27/05/2021	22/07/2021	No	Yes
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Protocol file	version v1.0	05/05/2021	22/07/2021	No	No