

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

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|--|---|---|
| <b>Submission date</b><br>19/07/2021   | <b>Recruitment status</b><br>No longer recruiting | <input checked="" type="checkbox"/> Prospectively registered<br><input checked="" type="checkbox"/> Protocol            |
| <b>Registration date</b><br>29/09/2021 | <b>Overall study status</b><br>Completed          | <input type="checkbox"/> Statistical analysis plan<br><input type="checkbox"/> Results                                  |
| <b>Last Edited</b><br>10/01/2025       | <b>Condition category</b><br>Cancer               | <input type="checkbox"/> Individual participant data<br><input checked="" type="checkbox"/> Record updated in last year |

## 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**

Dr Eleanor Mishra

**Contact details**

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## Additional identifiers

EudraCT/CTIS number

Nil known

**IRAS number**

295614

**ClinicalTrials.gov number**

Nil known

**Secondary identifying numbers**

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

**Secondary study design**

Cohort study

**Study setting(s)**

Hospital

**Study type(s)**

Treatment

## **Participant information sheet**

See study outputs table

## **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 measure**

The size of pleural effusion measured using chest X-ray on day 0 and day 7

## **Secondary outcome measures**

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

## **Overall study start date**

15/06/2021

## **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

## **Age group**

Adult

## **Lower age limit**

18 Years

## **Sex**

Both

## **Target number of participants**

Planned Sample Size: 240; UK Sample Size: 240

## **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**

England

United Kingdom

**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  
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LE1 5WW

## **Sponsor information**

### **Organisation**

Norfolk and Norwich University Hospitals NHS Foundation Trust

### **Sponsor details**

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### **Sponsor type**

Hospital/treatment centre

### **Website**

<http://www.nnuh.nhs.uk/>

### **ROR**

<https://ror.org/01wspv808>

## **Funder(s)**

### **Funder type**

Government

**Funder Name**

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

## Results and Publications

**Publication and dissemination plan**

Planned publication in a high-impact peer-reviewed journal

**Intention to publish date**

31/03/2025

**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? |
|---|--------------|--------------|------------|----------------|-----------------|
| <a href="#">Participant information sheet</a> | version v2.0 | 27/05/2021   | 22/07/2021 | No             | Yes             |
| <a href="#">Participant information sheet</a> | version v2.0 | 27/05/2021   | 22/07/2021 | No             | Yes             |
| <a href="#">Participant information sheet</a> | version v2.0 | 27/05/2021   | 22/07/2021 | No             | Yes             |
| <a href="#">Protocol file</a>                 | version v1.0 | 05/05/2021   | 22/07/2021 | No             | No              |
| <a href="#">HRA research summary</a>          |              |              | 28/06/2023 | No             | No              |