

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

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

eleanor.mishra@nnuh.nhs.uk

Contact information

Type(s)

Scientific

Contact name

Dr Eleanor Mishra

Contact details

Norfolk and Norwich University Hospital NHS Foundation Trust

Department of Respiratory Medicine

Norfolk and Norwich University Hospital

Colney Lane

Norwich

United Kingdom

NR4 7UY

+44 (0)1603286286

eleanor.mishra@nnuh.nhs.uk

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
United Kingdom
LE1 5WW

Sponsor information

Organisation

Norfolk and Norwich University Hospitals NHS Foundation Trust

Sponsor details

c/o Julie Dawson
Colney Lane
Colney
Norwich
England
United Kingdom
NR4 7UY
+44 (0)1603 647882
julie.dawson@nnuh.nhs.uk

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?
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
Protocol file	version v1.0	05/05/2021	22/07/2021	No	No
HRA research summary			28/06/2023	No	No