Participant information sheet

REPEAT Study: Can we predict how quickly pleural fluid will come back after drainage?

We'd like to invite you to take part in our research study. Joining the study is entirely up to you. Before you decide whether to take part, we would like you to understand why the research is being done and what it involves.

The study is designed to find out if we can predict how quickly pleural fluid will come back after drainage. You have been invited to be part of this study because you have a pleural effusion and you are coming to the Pleural Clinic to have the fluid drained off.

Please have a look through this information sheet before you come to the Pleural Clinic and think about whether you would like to be involved. When you come, one of our team will go through the information sheet with you to help you decide whether you would like to take part and answer any questions you have. Please feel free to show this information sheet to friends, family and other health professionals and talk to them about the study. Please take as much time as you need to decide whether you would like to participate in our research (although we will need to know your decision before you have your fluid drained).

1. What is pleural fluid?

Pleural fluid is fluid which has built up in the space between the lung and the chest wall. This collection of fluid is called a pleural effusion. We treat it by draining it off.

2. Why are we doing this study?

After pleural fluid is drained off, it may build up again. Often, patients ask us how quickly the fluid will come back. At the moment, we can't answer this question. We hope that by studying how quickly the fluid builds up in our patients, in the future we will be able to answer that question. This means we can plan when to drain the fluid again.

3. What's involved in the study?

If you decide to take part in the study, you will be asked some extra questions about your symptoms before you have the fluid drained and complete a questionnaire about your quality of life.

While you are having the fluid drained, we may measure the pressure in the pleural space using a pressure gauge attached to the aspiration equipment. This is called pleural manometry and is done during the aspiration so it does not take additional time. It is a non-invasive technique and there are no risks associated with this

procedure. We only need a small number of participants to have this assessment, so you may not be asked to participate in this part of the study if we have already collected sufficient data.

You may also have some extra blood tests and pleural fluid samples taken. These extra samples are optional and you can still take part even if you do not wish to have these extra samples taken. We will collect about 10mls (about 2 teaspoonfuls) of blood and 10mls of pleural fluid at your first visit. These samples will be taken at the same time as your standard clinical samples.

You will have an ultrasound after the fluid has been drained. This ultrasound is additional to standard care - you wouldn't normally have it if you were not involved in this study.

You will be asked to complete a short daily diary about your breathing over one week. To complete this diary, you will be asked to mark on a single horizontal line of 10cm how breathless you are feeling on the day. This should not take more than a few minutes each day.

When you come back to Pleural Clinic for results of your fluid analysis 1 week after your drainage procedure, you will have a chest X-ray at this appointment and further drainage if necessary. This is part of standard medical care that you would have whether you wish to be part of this study or not. At this visit, we will also ask you to complete a short questionnaire called EQ-5D. This questionnaire consists of statements relating to your mobility, self-care, usual activities, pain/discomfort and anxiety and depression. You can either complete the questionnaire on paper yourself or you can have the questions read to you and the researcher will record your responses if this is easier.

You will not have to come to hospital any extra times to be part of the study but we will contact you at 1 month and 3 months after your procedure to find out if you have needed any further pleural procedures or other treatments, or if you have had any emergency hospital attendances. We will also ask you to complete the EQ-5D again over the phone at 3 months.

4. Will my General Practitioner/family doctor (GP) be informed of my participation?

No, we will not be contacting your GP to inform them of the study but if you wish to discuss your participation with your GP you are free to do so.

5. Where is the study being done?

The study is happening at the Pleural Clinic at five hospitals in England in Leicester, Plymouth, Oxford, Bristol and Norwich.

6. How long will the study last?

The study will run for 3 years from 2021.

7. What are the possible benefits of taking part?

There are no specific benefits to taking part in this study for you but we hope the results of the study will help us improve the care for other patients with a pleural effusion in the future.

8. What are the possible disadvantages and risks of taking part?

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 you are part of the study or not. However, you will have an additional thoracic ultrasound, pleural manometry and we will ask you to donate samples of your blood and pleural fluid, complete the daily breathlessness diary and complete the EQ-5D questionnaire which are all beyond standard of care and will require some extra time on your part.

9. What if something goes wrong?

This is a study with no intervention except an optional additional blood and fluid samples, an ultrasound and some questionnaires, so there is no additional risk to participants when taking part in this study compared with standard care. If you have a concern about any aspect of this study, you should ask to speak to the researchers who will do their best to answer your questions. If you wish to complain or have any concerns about any aspect of the way you have been approached or treated during the course of this study, then you should contact the Patient Advice and Liaison Service (PALS) at your hospital.

Email:

Telephone:

10. What will happen if I don't want to carry on with the study?

You are free to leave the study at any time. This will not affect your clinical care in any way and you do not need to give a reason. If you do decide to leave the study, all samples and data already collected will be retained.

11. How will my information be kept confidential?

If you decide to be involved in the study, you will be given a participant number. All data collected will be identified using your participant number and will not have your name on. We will keep all your information about you safe and secure.

12. What will happen to my data?

Data protection regulation requires that we state the legal basis for processing information about you. In the case of research, this is 'a task in the public interest.' The Norfolk and Norwich University Hospital NHS Foundation Trust is the data controller and is responsible for looking after your information and using it properly. We will be using information from you and your medical records in order to undertake this study and will use the minimum personally-identifiable information possible. Once we have finished the study, we will keep some of the data so we can check the results. We will write reports in a way that no one can work out that you took part in the study. We will keep identifiable information about you for 6-12 months after the study has finished. This excludes any research documents with personal information, such as consent forms, which will be held securely at the Norfolk and Norwich University Hospital NHS Foundation Trust for 5 years after the end of the study.
If you agree to your samples being used in future research, your consent form will be held until the samples have been depleted or destroyed.

Your local study team will use your details e.g. name, NHS number, home address, and contact details, to contact you about the research study, and to oversee the quality of the study. They will keep identifiable information about you from this study for 6-12 months after the study has finished.

13. What are your choices about how your information is used?

You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have.

If you choose to stop taking part in the study, we would like to continue collecting information about your health from your hospital. If you do not want this to happen, tell us and we will stop.

We need to manage your records in specific ways for the research to be reliable. This means that we won't be able to let you see or change the data we hold about you.

14. Where can you find out more about how your information is used?

You can find out more about how we use your information sample

- at www.hra.nhs.uk/information-about-patients/
- our leaflet available from www.hra.nhs.uk/patientdataandresearch
- by asking one of the research team
- by sending an email to info.gov@nnuh.nhs.uk or

- by ringing us on 01603 286286

15. What will happen to the results of this study?

These results will be analysed and reviewed by our team and presented at national conferences and published in a scientific journal. We will also discuss them with members of our patient and public research group. Data and samples collected may be used in future research or shared with other researchers.

16. Who is leading and funding this study?

This study is led by Dr Eleanor Mishra with the support of the Norfolk and Norwich University Hospital. It is funded by a Research for Patient Benefit Grant from the National Institute for Health Research.

17. How have patients and the public been involved in this study?

The idea for this study came from our patients coming to Pleural Clinic who often asked us 'when will the fluid come back?' after they had had it drained. At the moment, we can't answer this question accurately. We hope that this study will help us answer this question accurately in the future. Our patients have been involved in designing the study.

18. Who has reviewed this study?

This study has been reviewed by an independent Research Ethics Committee which is responsible for safeguarding the rights, safety, dignity and well-being of research participants.

19. What will happen to the samples I give?

If you agree to give your blood and pleural fluid samples, they will be processed and stored at your local hospital for the duration of the study. We will later use them for different analyses to see if we can identify proteins in these samples that can predict how quickly the fluid will reaccumulate. Any remaining samples will be stored long term for use in future ethically approved research in a local research tissue biobank (a resource of tissue and blood samples donated by patients for use in medical research).

20. Consent process

If you agree to be part of the study, you will sign a consent form. You will be given a copy of this form to keep.

During the consent process, we will explain that if you lose capacity to consent throughout the study, the study team will retain and use the study data and samples collected up to that point.

21. Will I be reimbursed for taking part?

There will be no reimbursement for your participation in this study as all the study visits will be done at the same time as your standard care visits.

22. Additional support

If during the study you become worried or distressed at any point, please feel free to discuss your concerns with the research team. If you need additional support from outside the research team, you can contact your local Specialist Nurse at ……

There is also support available from different organisations such as:

- https://www.macmillan.org.uk/cancer-information-and-support
- https://www.maggies.org/cancer-support/
- https://www.cancerresearchuk.org/about-cancer/coping

You can also speak to the Samaritans on 116 123. Alternatively, you can contact your GP or phone 111 or use the 111 online service (https://111.nhs.uk) outside of standard office hours.

Contact details and further information

Principal Investigator:

Email:
Telephone:

Research Nurse:

Email:

Telephone:

Thank you for taking your time to read this information sheet.