Participant Information Sheet (PIS)

# Can treatment of cancer-related fluid around the lung (Malignant Pleural Effusion) help improve fatigue? A questionnaire-based study

## We invite you to take part in a research study

- Before making a decision about whether you would like to take part, it is important to understand the following information.
- This information sheet includes details of why we are doing the study and what to expect if you decide to take part.
- Feel free to ask any questions you may have about the study.
- You may wish to talk about the decision with family or friends.
- You are free to decide whether or not to take part. If you decide not to, this will have no impact on the usual care you get from your doctor.

**Contents:**

## 1- Background information

Your lungs have a smooth covering called pleura which let your lungs expand without rubbing on the inside of your chest. Normally the space between these layers (pleural space) is very small. Sometimes due to illness fluid builds up in this space (pleural effusion). This makes it more difficult for your lungs to expand and so breathing is more difficult. You have been sent to this special "pleural clinic" to see a doctor who specialises in the different ways this fluid can be removed. The doctor will discuss the different possible procedures and you will decide together which is the best option for you.

Previous research has shown that these different techniques are helpful for improving breathlessness. We know that many people with fluid around the lungs, especially when related cancer, feel fatigued. Fatigue can sometimes be a person's most troublesome problem as it can affect whether they are able to look after themselves and continue to do activities they enjoy.

This study is to see if the techniques to remove fluid from around the lungs can also help improve levels of fatigue. This information is important as it will help future patients decide whether having one of the procedures is right for them.

The following information is to help understand what this study involves.

## 2- What would taking part involve

You will decide together with your doctor which is the best treatment for you. Taking part in the study will not change the treatment you receive. If you decide to take part, then you will be invited to fill in questionnaire with 13-questions about how fatigued you have felt over the past week before having your decided treatment. We will then telephone you 7 days after your procedure to ask you the 13-questions again. We will do the same again at 14 and 30 days after your procedure. You will be answering the same questionnaire 4 times to see if your answers change over time. We will also ask your permission to collect some information about you that may contribute to your fatigue, this includes:

- Age
- Sex (male or female)
- Your diagnosis (such as type/location of cancer)
- Time since diagnosis (number of months/years)
- Time since last chemotherapy or radiotherapy (if applicable)
- Whether you have other illnesses which may potentially contribute to fatigue levels (for example heart or lung disease or anxiety/depression)
- Patient Outcome Score (POS) which are questions about which symptoms you are experiencing such as level of current breathlessness or pain.
- Size of pleural effusion (small or large) & if present in one or both lungs.
- Performance status (general fitness level)

- Blood results (Haemoglobin level & Creatinine) if already taken as part of your usual care (i.e. you will not need an additional blood test for this study).

Only the research team will have access to this data, which will be treated confidentially. The data will be anonymised and nobody will be able to identify you from the results.

## 3- What are the benefits of taking part?

There is no direct benefit to you taking part, but your involvement could help other patients like you in future.

## 4- What are the possible disadvantages of taking part?

The only disadvantage is the time taken to complete the short (13 question) questionnaire. The questionnaire will take at most 5 minutes to complete. You will do this in person on the day of your procedure then will receive a telephone call 3 times over the following month to repeat the questions.

## 5- Supporting information

### 5.1 What if something goes wrong?

Talking about medical problems can sometimes cause people to feel upset. If completing the questionnaire causes you any upset or distress, then please let the research team know who will be able to discuss your concerns and provide support. They may discuss with

you referring you for further support if needed (such as referral to a lung cancer specialist nurse).

If you have any other concern about any aspect of the study please contact the research team using the details below. If you would prefer to speak to someone independent of the research team then your usual doctor who invited you to take part can advise you further on the relevant complaints procedure. Alternatively, you may choose to make a complaint directly contact PALS (Patient Advice & Liaison Service 0800 032 02 02).

## 5.2 What will happen if I change my mind?

Your involvement is entirely voluntary, and you may leave the study at any time. If you leave the study we will use the information which has already been gathered but not collect any further information from you or your records.

## 5.3 How will we use information about you?

We will need to use information from you and from your medical records for this research project.

This information will include your NHS number, name and contact details. People will use this information to do the research or to check your records to make sure that the research is being done properly.

People who do not need to know who you are will not be able to see your name or contact details. Your data will have a code number instead.

We will keep all information about you safe and secure.

Once we have finished the study, we will keep some of the data so we can check the results. We will write our reports in a way that no-one can work out that you took part in the study.

**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.
- 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.
- If you agree to take part in this study, you will have the option to take part in future research using your data saved from this study within Northumbria Healthcare NHS Foundation Trust. You can opt in or out of this option on the consent form.

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

You can find out more about how we use your information

- at www.hra.nhs.uk/information-about-patients/
- by asking one of the research team
- by sending an email to donna.wakefield1@nhs.net

## 5.4 What will happen to the results of this study?

The results will be analysed and submitted for publication in a peer reviewed journal. This will be a summary of all results and will be anonymous with no patient identifiable information. A summary will be available to all participants and you can choose whether you wish

to receive this or not. Your GP will not be informed of your involvement in this study.

## 5.5 Who is organising and funding this study?

This student study as part of a Masters project through Newcastle University. Northumbria Healthcare NHS Foundation Trust are the sponsor for this study with administration costs supported by a company called Rocket Medical (manufacturer of some of the equipment used to treat pleural effusions). The researchers will receive no payment for this study. Unfortunately, no funding is available to pay you for your involvement in this study, however it will not cost you anything to take part.

## 5.6 How have the patients and public been involved in this study?

The idea for this study and this leaflet has been reviewed by patients for feedback on its acceptability.

## 5.7 Who has reviewed this study?

All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee, to protect your interests. This study has been reviewed and given favourable opinion by an independent Research Ethics Committee.

## 5.8 Further information and contact details

Dr Donna Wakefield
Consultant in Palliative Medicine
University Hospital of North Tees,
Farndale House,
Stockton-Upon-Tees
TS19 8PE

Donna.wakefield1@nhs.net

Number: 07825503176

6- Participant Information Sheet (PIS) SUMMARY SHEET

# Can treatment of cancer-related fluid around the lung (Malignant Pleural Effusion) help improve fatigue? A questionnaire-based study

You will be seen by the usual pleural/lung doctor about the fluid around your lung(s) and decide which treatment is best for you.

The doctor will ask if you would be interested in taking part in a study to learn about whether treatments for fluid around the lungs (such as the treatment you are have decided on) may also help patients fatigue levels.


If you are interested, then the researcher in clinic will come and discuss the study with the patient and go through the Participant Information Sheet.

If you would like to take part then you will be asked to sign a consent form.

The researcher will then ask you to complete a 13-question survey about how fatigued has/has not affected you over the past 7 days.

You will then have your treatment as planned

**(the study has no impact on your treatment).**

The researcher will contact you by phone to repeat the 13 survey questions 7, 14 and 30 days later to see if there has been any change in you fatigue levels.

As multiple other factors can also impact on fatigue the researcher will also gather some information from your medical notes (as described in the information pack).

In this research study we will use information from you & your medical records. We will only use information that we need for the research study. We will let very few people know your name or contact details, and only if they really need it for this study.

Everyone involved in this study will keep your data safe and secure. We will also follow all privacy rules.

At the end of the study we will save some of the data in case we need to check it (and if you agree for future research). We will make sure no-one can work out who you are from the reports we write.

# CONSENT FORM

Version 6 (release date 26.07.2020)

IRAS ID: 276451

Site code (circle): NTGH / WGH/NSECH/HGH

CI: Dr Donna Wakefield

Participant ID number:

NHS
Northumbria Healthcare
NHS Foundation Trust

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Please initial box

1. I confirm that I have read the information sheet dated 26.07.2020 (version 6) for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily. ☐
2. I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason, without my medical care or legal rights being affected. ☐
3. I understand that relevant sections of my medical notes and data collected during the study, may be looked at by individuals from regulatory authorities or from the NHS Trust, where it is relevant to my taking part in this research. I give permission for these individuals to have access to my records. ☐
4. I understand that the information collected about me will be used to support other research in the future and may be shared **anonymously** with other researchers. ☐
5. I understand that the information held and maintained by Northumbria Healthcare NHS Foundation Trust may be used to help contact me or provide information about my health status. ☐
6. I DO/do NOT want my data to be used in future research. (please delete as appropriate) ☐
7. I DO/do NOT want to receive a summary of the study results (please delete as appropriate) ☐
8. **I agree to take part in the above study.** ☐

| Name of Participant | Date | Signature of Participant |
|---|---|---|

When completed: 1 for participant; 1 for researcher site file; 1 to be kept in medical notes.

| Name of Person taking consent | Date | Signature of person taking consent |
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