Patient Information Sheet

Pilot feasibility study to determine the clinical effectiveness of neural respiratory drive (NRD) to predict COPD exacerbations at home

Introduction

Guy's and St Thomas' NHS Trust would like to invite you to consider taking part in a study to investigate if it is possible to measure the electrical activity of the breathing muscles of the chest by applying stickers to the chest wall. These are connected to a device which uses the activity of your breathing muscles to show how much effort you need to breathe. This is called 'drive' to breathe (or Neural Respiratory Drive).

We have tested this measurement on patients admitted to hospital with an 'exacerbation of COPD'. This is a worsening of symptoms, such as breathlessness, cough or sputum (phlegm) production, in patients affected by Chronic Obstructive Pulmonary Disease. This is a common and important condition, also known as emphysema or bronchitis, which is often caused by smoking. We have found that 'drive' to breathe measurements can tell us whether patients are improving or not when they are admitted to hospital with an exacerbation of COPD. We think it might tell us whether patients are developing another exacerbation after they are discharged from hospital.

Before you decide to enter this study, it is important to understand why the research is being done and what it will involve. Please read the following information carefully and discuss it with whoever you choose; friends, relatives and/or your doctor. Please ask if you want us to clarify anything or if you would like more information. You do not need to make up your mind straight away.

What is the purpose of the study?

COPD is an important problem for patients. It can make them feel unwell and they may need to be admitted to hospital, which can have a big impact on their quality of life. In this study, we want to see whether measuring 'drive' to breathe can identify an exacerbation of COPD up to 30 days after patients are discharged from hospital with an exacerbation of COPD. If it can, in the future this could mean treatment (for example steroids and/or antibiotics) could be started sooner which could avoid being readmitted into hospital.

Why have I been invited to take part?

You have been invited to participate because you have been admitted to hospital because of an exacerbation of COPD. Our monitoring device has been used most often in patients like you and we feel that you are in this group most likely to benefit from the technology. We will include 30 patients in total.

Do I have to take part?

No, your participation is voluntary. We believe that this is an important study that could improve the way we monitor patients during and after exacerbations of COPD. However it is your decision to take part. This information sheet is for you to keep. If you do decide to take part, you will be asked to sign a consent form and you will receive a copy of this. If you decide to take part, you are still free to withdraw at any time without needing to give a reason. If you decide not to participate in this study or to withdraw following starting the study, it will not affect the standard of care you receive.

What will happen to me if I take part and what study procedures and tests will be involved?

If you consent to take part in the study, we will collect data routinely taken as part of your normal care, including:

- Age, height, weight
- Brief medical history
- If you had a chest x-ray when you were admitted to hospital, we will look at it
- Oxygen and carbon dioxide levels from the blood, and routine blood tests looking at your blood count, kidney function and infection markers. We will look at the tests already taken by the doctors and nurses looking after you. We do not need to take any extra blood tests.
- Simple blowing tests (also called 'spirometry' or 'lung function tests') to assess your airways and breathing muscle function
- 'Vital signs' (heart rate, breathing rate, blood pressure and oxygen levels)

What is required from me for the purpose of this study:

- When you first agree to the study, the research team will:
  - Help you to complete two questionnaires which assess how much your breathing problem affects you (10 minutes)
  - Measure your waist and hip circumference

- The research team will visit you every day while you are in hospital to:
  - Measure your vital signs and ask your medical team for updates (10 minutes)
  - Measure your 'drive' to breathe (see below for details) (10 minutes)
  - Help you to complete a symptom questionnaire (10 minutes)

- At home, when you are discharged from hospital, the research team will:
  - Give you an activity wrist watch which measures your physical activity (see below for details)
  - Give you a diary to record your symptoms every day (5 minutes)
  - Look at the most recent blood tests you have had
  - Visit you every day at home to measure your 'drive' to breathe and help you to complete a symptom questionnaire (30 minutes)
  - Look at your symptom diary (5 minutes)
  - Help you to perform simple blowing tests once a week (5 minutes)

The study will take place from the day you are admitted to hospital until 30 days after you are discharged, or until you are readmitted to hospital (whichever is sooner). The research team will arrange home visits at times that are convenient for you. Home visits will take less than one hour.

Measuring 'drive' to breathe:
The measurement of your 'drive' to breathe involves the researcher placing two stickers (similar to heart tracing, or ECG, stickers) on your chest and one on your shoulder, and oxygen tubing (nasal cannula) into your nostrils. These are connected to the measuring device. When you are resting comfortably and breathing as usual, the device will monitor the activity of your breathing muscles and turn it into electronic data which we can study. At the end of the recording period (approximately 6 minutes) you will be asked to perform 6 'sniffs', which are sharp inhalations through your nose.

Measuring physical activity
The physical activity monitor that you will be given if you agree to the study is a watch-like device that you wear on your wrist. It records the amount of time you spend asleep and awake and the amount of time you spend being active and resting. The data the device records is de-identified and it does not track your movement or know your location. You will be asked to wear the watch for the whole time you are part of the study but you can take it off for short periods, such as when you go to the bathroom to wash. The watch is waterproof, so you do not need to worry if it gets wet or if you prefer to wear it when showering or bathing. We will collect the device from you at the end of the study.

What are the possible disadvantages and risks of taking part?

All of the tests are not invasive and involve little discomfort, other than the time taken to perform them. The adhesive pads and cream used to clean the skin before monitoring and the physical activity monitor can rarely cause minor irritation. The blowing tests (because they require some effort) may at times be uncomfortable, but are all safe. There is no risk of radiation additional to your normal care (your medical team may ask you to have a chest x-ray).

We do not perceive any other disadvantages in taking part as all participants will receive the current 'best practice' medical treatment. The research team are not involved in making decisions about your care. You should complete the course of antibiotics and/or steroids and any other treatments that your medical team advise.

This study will require time and commitment from the patients enrolled, which the investigators appreciate and are very grateful for. All participants will be closely followed up by the research team who are experienced in the management of patients with COPD.

What are the possible benefits of taking part?

Whilst we do not expect there to be a direct benefit for participants of the study we hope that the study will provide information to improve the treatment of acute exacerbations of COPD and has the potential to avoid being readmitted into hospital.

Will my taking part in this study be kept confidential?

Unless you request otherwise, your General Practitioner and your usual respiratory consultant will be told that you have decided to take part in this study. If you have private medical insurance you should inform your insurer that you are taking part in a research study.

The data obtained while you are in this study, including health records will remain strictly confidential at all times However, it may need to be made available to others, including Ethics Committee members and Regulatory Authorities.

By signing the consent form you agree to this access for the current study. We will take steps to protect your personal information and will not include your name on any forms, reports or publications. Personal data, which may be sensitive (e.g. date of birth), will be collected and processed, but only for research purposes in connection with this study. If you withdraw from the study, we will no longer collect your personal information, but we may use information already collected. You can request at any time to have your personal data deleted.

To protect your privacy, your data will be de-identified with a subject number, not your name. Researchers use this number to keep track of information and only they can link your subject number to your name. Therefore, the research team, the sponsor (Guy's and St Thomas' NHS Foundation Trust) and their representatives at the Research Ethics Committee and Health Research Authority (who protect and promote the interests of patients in research) may have access to your individual research data. At the end of the research, relevant study results will also be provided, without revealing your name and personal details, to a commercial third party (Philips and Affiliates, who provide the devices that measures 'drive' to breathe and physical activity) for internal research and development purposes only. This means that your name and all other personal details that could identify you will be removed from the data before transfer to the third party. Information will only be used to analyse the de-identified data and not your performance. De-identified data will be stored for up to 5 years as it may be used to help future research.

What will happen to the results of the research study?

The results of the study will be available at the end of the study after the data analysis is complete. A lay summary will be provided by the trial group to the participants and the Respiratory Critical Care Research Advisory Group. The results will be shared with participants via a letter at the end of the trial. This will be sent to all participants outlining the results and any subsequent changes in medical practice. We will present the data at national and international medical meetings. Furthermore, we will aim to publish the data in a peer-reviewed medical journal. You will not be identified in any report or publication.

What if there is a problem?

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. You can contact a member of the research team by calling the Lane Fox Research Office on 020 7188 8070. If you have a complaint, you should talk to your research doctor who will do their best to answer your questions. If you remain unhappy, you can make a formal complaint through the NHS complaints procedure. Details can be obtained through the Guy's and St Thomas' Patient Advisory Liaison Service (PALS) (see details overleaf). This study is insured by Guy's & St Thomas' NHS Foundation Trust under the Clinical Negligence Scheme for trials. All professional staff involved in the study hold professional indemnity to work within Guy's and St Thomas' NHS Trust. In the event that you are harmed during the research and this is due to negligence then you may have grounds for legal action for compensation against Guy's and St Thomas NHS Trust but you may have to pay your legal costs. The normal NHS complaints mechanisms are still available to you.

Is my doctor being paid for including me in the study?

Neither the doctors nor other members of staff are being directly paid for this study.

Do I receive any financial compensation if I take part to this study?

There is no payment made to you for taking part in this study.

What happens when the research study stops?

After completion of the study you will continue to be managed by your current doctors, who throughout the study will remain in charge of your medical care.

Who is funding the study?

The study is funded by the National Institute for Health Research Biomedical Research Centre at Guy's and St Thomas' NHS Foundation Trust. Philips and Affiliates provide the device to measure 'drive' to breathe and the physical activity monitors.

Who is sponsoring the study?

The study is sponsored by Guy's and St Thomas' NHS Foundation Trust.

Who has reviewed the study?

The study has been approved by the Westminster National Research Ethics Service Committee.

CONTACT TELEPHONE NUMBERS:

If at any time you are concerned or require additional information, please contact the Lane Fox Research Office on 020 7188 8070.

Chief Investigator
Professor Nicholas Hart, MB BS Bsc PhD MRCP FFICM
Clinical & Academic Director
Lane Fox Respiratory Unit,
Guy's & St Thomas' Foundation Trust,
Westminster Bridge Road,
London SE1 7EH.
Tel: 020 7188 8070

Principle Investigator
Dr Patrick Murphy, BSc PhD MBBS MRCP
Consultant in Home Mechanical Ventilation,
Respiratory Medicine & Critical Care Medicine,
Lane Fox Respiratory Unit,
Guy's & St Thomas' Foundation Trust,
Westminster Bridge Road,
London SE1 7EH.
020 7188 8070

Clinical Research Fellow
Dr Rebecca D'Cruz
Lane Fox Respiratory Unit,
Guy's & St Thomas' Foundation Trust,
Westminster Bridge Road,
London SE1 7EH.
Tel: 020 7188 8070

Trial Co-ordinator
Gill Arbane
Lane Fox Respiratory Unit,
Guy's & St Thomas' Foundation Trust,
Westminster Bridge Road,
London SE1 7EH.
Tel: 020 7188 8070

You can also contact PALS for independent information regarding research at Guy's and St Thomas' NHS Foundation Trust:
Patient Advisory Liaison Service, c/o KIC,
Ground floor, North Wing,
St Thomas' Hospital,
Westminster Bridge Road,
London SE1 7EH.
Tel: 020 7188 8801

Guy's and St Thomas' NHS
NHS Foundation Trust

DOCUMENTATION OF CONSENT

First name:	Family name:	Date of birth:
Trial doctor's name:		Hospital number:

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Your Consent	Subject Initials
1. I confirm I have read and understand the information sheet version 1.5, dated 4th September 2017, for the above study. I have had the opportunity to consider the information and ask questions. I am over 18 years old.	
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. I confirm that I have been informed how to contact the research team should I need to.	
3. I consent to undergo breathing tests and tests of breathing muscle activity. I consent to questionnaires regarding my symptoms and my medical history. I consent to the research team to look at the blood test results described to me. I have had the research protocol explained to me.	
4. I understand that the clinical information gathered about me can be stored by Guy's & St Thomas' NHS Foundation Trust (GSTFT). The GSTFT Chief Investigator will be the legal custodian of this material. I understand that clinical information can only be used in research projects that have received the approval of a regional Ethics Committee.	
5. I understand that relevant sections of my medical notes and data collected during the study may be looked at by individuals from the research group, 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. My identity will always be kept confidential.	
6. I understand that de-identified information collected about me may be used to support other research in the future, and may be shared in de-identified form with other researchers including Philips and its Affiliates.	
7. I understand that my doctor and myself will be informed if any results of the medical tests done as part of research are important for my health, where such results have not been de-identified.	
8. I agree to my General Practitioner (GP) being information of my participation in the study.	

Subject Name (print): _____

Signed by Subject: _____ Date: _____

(Please date your own signature at the time of signing)

Investigator Name (print): _____
(Principal investigator or authorised designee)

I have answered all questions about the study and discussed the meaning and scope of this informed consent and signed it in the presence of the participant.

Signed by Investigator: _____ Date: _____

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