CasCaDe:

A Comparison and Validation Study of Cough Challenge Responses Evoked Using Two Different Bronchial Provocation Systems

Participant Information Sheet (PIS)

You are being invited to take part in a research study. Before you decide whether to take part, it is important for you to understand why the research is being conducted and what it will involve. Please take time to read the following information carefully before deciding whether to take part and discuss it with others if you wish. Please ask if there is anything that is not clear or if you would like more information. Thank you for taking the time to read this.

About the research

- Who will conduct the research?

This study is being carried out by a team of trained doctors, physiologists and researchers under the supervision of Professor Jacky Smith from the University Of Manchester School Of Biological Sciences. A mix of University of Manchester researchers and staff from Manchester NHS Foundation Trust will be working on the study.

- What is the purpose of the research?

Cough is one of the body's protective reflexes which is used to clear the airways of irritating material or phlegm yet it is the most common complaint for which people seek medical advice. Cough is a common feature of a number of different chest conditions and can be troublesome and associated with poor quality of life. Cough challenge tests are used in research to measure how sensitive a person's cough reflex is. These tests enable us to compare cough sensitivity between different people and different chest conditions, or before and after medication. We are doing this research because the current equipment being used for cough challenge testing is being withdrawn from use and it is important that we find an alternative which produces reliable results comparable with the previous research carried out.

We are aiming to recruit 12 heathy volunteers to take part in the study.

- Will the outcomes of the research be published?

It is intended that the results of the study will be presented at conferences and published in medical journals so that we can explain our research results to the medical community. Your identity will be kept anonymous and your name will never appear in any report or publication arising from this study.

We will also write about the research findings in our chronic cough newsletter, which is distributed to patients in our chronic cough clinic and sent to previous research participants who have subscribed to receive it.

- Disclosure and Barring Service (DBS) Check

All members of the research team have relevant DBS checks in place.

- Who has reviewed the research project?

All research in the NHS is approved by an independent group of people called a Research Ethics Committee. The Research Ethics Committee is made up of experts, non-experts and members of the general public. Together they review research applications to ensure your safety, rights, wellbeing and dignity are protected at all times. This study has been reviewed and given a favourable opinion by the University of Manchester Research Ethics Committee.

- Who is funding the research project?

This research is being carried out by experienced research staff at the Manchester Clinical Research Facility, Wythenshawe Hospital. The study is being funded by the NIHR Biomedical Research Centre.

What would my involvement be?

- What would I be asked to do if I took part?

If you agree to take part after reading this information sheet, an experienced researcher will contact you to explain the study in more detail and give you the opportunity to ask any questions you may have. You will then be asked to attend Wythenshawe Hospital for visit 1.

Due to the current COVID-19 pandemic, we have made some adjustments to the way in which this research study will be conducted that ensures we are adhering to the latest government advice in relation to social distancing as well as taking all reasonable precautions in terms of limiting the spread of the virus. You should carefully consider all of the information provided below before deciding if you still want to take part in this research study. If you choose not to take part, you need to inform the research team. If you have any additional queries about any of the information provided, please speak with a member of the research team.

Are there any additional considerations that I need to know about before deciding whether I should take part?

If you agree to take part in this study you will need to attend the hospital and therefore have contact with other patients, research participants and members of staff. However, social distancing is still being practiced on the hospital site and a number of processes are in place to minimise the risk of infection to all individuals.

What additional steps will you take to keep me safe while I take part?

There are processes and procedures in place at the NIHR CRF to minimise the risk of coronavirus transmission. Both you and all staff members will be wearing appropriate PPE, provided by the NIHR CRF. The number of people permitted in any room in the CRF has been assessed so that adequate social distancing can be achieved, only rooms with adequate ventilation will be used for study visits, and risk assessments have been carried out on all procedures. Adequate time will be left in between patient visits to allow for cleaning of all equipment and surfaces, and for full air exchange in the room.

Is there any additional information that I need to know?

We will contact you within the 24 hours before your visit to ensure that you or anyone in your household are not suffering from any symptoms of COVID-19. If you are, the visit will be rearranged. **If you are in a group vulnerable to COVID-19, or if you are shielding, you can discuss any concerns with the research team before agreeing to take part.**

Additional data use

Although it is unlikely, you may be contacted after your study visits for further details to assist tracking and tracing procedures, should there be concerns regarding infection risk.

What if the Government Guidance changes?

Should government guidance change during your participation on the study any updates to local policies and procedures will be discussed with you.

What if I have additional queries?

If you have any queries specific to COVID-19 then please contact the researcher(s) Cough Research Team on 0161 2091 5031 or cough.research@manchester.ac.uk.

<u>Visit 1</u>

This visit will last for approximately 1.5 hours.

A researcher will talk through the study again with you and answer any questions you may have. If you are still happy to take part, you will be asked to sign a consent form. With your permission, your GP will be informed of your participation in the study.

After giving consent, you will then be asked questions about your medical history, lifestyle and details of any medications you are taking. If you do take medications, it may be helpful to bring a prescription with you to allow us to accurately record your medications and the doses you take. Your height and weight will be measured and then you will be asked to perform a simple breathing test called spirometry. This involves inhaling as much air as you can and then blowing into a machine called a spirometer as fast as you can until your lungs are empty. You will be asked to wear a nose clip during the test to ensure that all of the air you blow out is captured. You will then be asked to perform a cough challenge which is a

test designed to measure how sensitive your cough is. The researcher will ask you to take a breath of a weak solution through a nebuliser which may or may not make you cough. The solution will contain diluted capsaicin which is a naturally occurring extract of red chilli peppers. Capsaicin has been used for many years to provoke cough and is known to be very safe. Once you have taken the breath, the researcher will measure how much you cough. The process will be repeated with the solutions getting gradually stronger. You will be asked to continue to breathe in the solution until you cannot tolerate it anymore, and then the test will be stopped. A small machine called a cough monitor will be attached to you during the test to capture your coughing. This will involve clipping a small microphone to the lapel of your clothing. At the end of the challenge, the breathing tests will be repeated to ensure that you have not experienced chest tightening, which can rarely occur in some people as a side effect of cough challenge.

The cough monitor will then be removed and you will be able to leave the department. This is the end of Visit 1.

All of the tests and assessments you undertake at this visit will determine if you are eligible to take part in the next part of the study. It may be that you are unable to proceed with the rest of the study. If there are concerns that the spirometry readings are abnormal and may indicate an undiagnosed disease/disorder then we would seek advice from a respiratory physician to make the necessary referrals.

Visit 2 (3-10 days after visit 1)

This visit will last for approximately 1 hour.

A researcher will check that you are still eligible and happy to continue with the study and ask if there have been any changes in your health since the last visit. You will then be asked to perform a cough challenge test. Different equipment to visit 1 will be used to perform this cough challenge. Breathing tests will be performed before the test and again after the test to make sure that you have not experienced chest tightening. The cough monitor will be re-attached to you just for the duration of the test to capture your coughing. This is the end of visit 2 and the end of the study.

- Will I be compensated for taking part?

At the end of your participation in the study, you will be paid £20 per visit to compensate you for your time and travel expenses to/from the hospital. We can also offer free parking.

- What happens if I do not want to take part or if I change my mind?

It is up to you to decide whether or not to take part. You do not have to take part if you do not wish to. Your decision will not affect the standard of care you receive now or in the future at Manchester University NHS Foundation Trust (MFT). You can let the research team know whether you are interested in taking part or not by emailing cough.research@manchester.ac.uk or calling 0161 291 5031. If you do decide to take part you will be given this information sheet to keep and will be asked to sign a consent form. If you decide to take part you are still free to withdraw at any time without giving a reason

and without detriment to yourself. However, it will not be possible to remove your data from the project once it has been anonymised as we will not be able to identify your specific data. This does not affect your data protection rights. If you decide not to take part you do not need to do anything further.

The cough challenge test will be recorded using a cough monitoring device. Audio recording of the challenge is necessary for the research team to count the number of times that you cough during the challenge. All recordings will be stored securely and are only listened to by the research team.

Data Protection and Confidentiality

- What information will you collect about me?

In order to participate in this research project we will need to collect information that could identify you, called "personal identifiable information". Specifically we will need to collect:

- Name and contact information
- You date of birth
- Your ethnicity
- Details of any relevant medical conditions or medications which you take
- The name and address of your GP

We will also make an audio recording of the cough challenge. The aim of this is only to analyse the number of coughs and anything which you say will not be used or analysed in any way.

- Under what legal basis are you collecting this information?

We are collecting and storing this personal identifiable information in accordance with data protection law which protect your rights. These state that we must have a legal basis (specific reason) for collecting your data. For this study, the specific reason is that it is "a public interest task" and "a process necessary for research purposes".

- What are my rights in relation to the information you will collect about me?

You have a number of rights under data protection law regarding your personal information. For example you can request a copy of the information we hold about you, including audio recordings.

If you would like to know more about your different rights or the way we use your personal information to ensure we follow the law, please consult our Privacy Notice for Research: https://documents.manchester.ac.uk/display.aspx?DocID=37095

- Will my participation in the study be confidential and my personal identifiable information be protected?

In accordance with data protection law, The University of Manchester is the Data Controller for this project. This means that we are responsible for making sure your personal information is kept secure, confidential and used only in the way you have been told it will be used. All researchers are trained with this in mind, and your data will be looked after in the following way:

Your study data, including your relevant medical history and cough recording, will be kept under a study participant number, not your name. The researcher will be able to link your study number back to your name using a log which will be kept in a secure, locked office only accessible to the research team. The data will not be shared and will not be removed from Wythenshawe Hospital.

Your personal data, including name and contact details, will be kept in a locked office in the North West Lung Research Centre, Wythenshawe Hospital. It will only be accessible to members of the research team. Data will be retained for 5 years, after which it will be destroyed.

Individuals from the University, the site where the research is taking place and regulatory authorities may need to review the study information for auditing and monitoring purposes or in the event of an incident.

Please also note that individuals from The University of Manchester or regulatory authorities may need to look at the data collected for this study to make sure the project is being carried out as planned. This may involve looking at identifiable data. All individuals involved in auditing and monitoring the study will have a strict duty of confidentiality to you as a research participant.

What if I have a complaint?

- Contact details for complaints

If you have a complaint that you wish to direct to members of the research team, please contact:

Prof Jacky Smith on 0161 291 5031 or cough.research@manchester.ac.uk

If you wish to make a formal complaint to someone independent of the research team or if you are not satisfied with the response you have gained from the researchers in the first instance then please contact

The Research Ethics Manager, Research Office, Christie Building, The University of Manchester, Oxford Road, Manchester, M13 9PL, by emailing: research.complaints@manchester.ac.uk or by telephoning 0161 306 8089.

If you wish to contact us about your data protection rights, please email dataprotection@manchester.ac.uk or write to The Information Governance Office, Christie Building, The University of Manchester, Oxford Road, M13 9PL at the University and we will guide you through the process of exercising your rights.

You also have a right to complain to the Information Commissioner's Office (https://ico.org.uk/concerns) about complaints relating to your personal identifiable information, Tel 0303 123 1113

Contact Details

If you have any queries about the study or if you are interested in taking part then please contact the researcher(s) **Cough Research Team on 0161 2091 5031 or cough.research@manchester.ac.uk.**