

CANcer Diagnosis Decision rules study
CANDID
Participant Information Sheet

What is the purpose of this research?

The majority of patients who come to their doctor with lung symptoms (for example cough) or bowel symptoms (for example loose stool) do not have anything seriously wrong. However, a very few people are at risk of cancer. We would like to help doctors diagnose cancer quickly so that potential high risk patients are detected sooner and unnecessary examinations are minimised for those patients that are low risk. This research is about finding what symptoms and examinations are best for predicting lung and bowel cancer.

Who is behind this research?

This research is being sponsored and co-ordinated by the University of Southampton in collaboration with other leading Universities throughout the country (Universities of Bristol, Manchester, Oxford, London, Nottingham, Birmingham and Keele). It is funded by the National Institute for Health Research (NIHR) National School of Primary Care Research (NSPCR) and has been approved by the South Central Oxford A Research Ethics Committee (REC). Your local NHS Trust Research and Development department have also reviewed it and has given their permission for it to be carried out in your area.

Why have I been chosen?

You have been asked to take part in this study because you have visited your GP with symptoms that we are interested in. This will help us develop a way for minimising unnecessary examinations for low risk people and develop a speedy diagnosis for high risk people. You will be one of 20,000 people with lung and bowel symptoms asked to take part in this research.

What do I have to do?

Your doctor or practice nurse will go carefully through the research and explain what you will be asked to do.

Step 1. Signing the consent form

If you are happy to take part we ask you to sign the consent form. This can be done straight away at the GP surgery. Or, if you prefer, you can take it home and discuss the study with friends and family, or with the study team. Signed consent forms are sent to the study team in the FREEPOST envelope provided. This needs to be done within a week of your visit to the GP. During your appointment your GP will record some information about your symptoms on a secure website. This information will not be available to us, the research team, until we have received your signed consent form.

Step 2. Blood or saliva sample

A blood sample can be taken at your practice immediately after you have spoken to your GP, or you may have to make a separate appointment. The surgery will send it for storage at the University of Southampton Faculty of Medicine Tissue Bank (Human Tissue Authority Licence No: 12009) until it can be analysed. If you do not wish to provide blood you can give a saliva sample.

Step 3. Information about you

At home we will ask you to fill in a questionnaire on a secure website (or you may be able to complete it on a paper copy) about your lifestyle. It should take no longer than 60 minutes; the website will allow you to complete this in several sessions. You will receive a log-in and link to the website with the questionnaire by email.

Step 4. Checking on your progress

A member of your surgery or a member of the research team will look at your medical records and official registers over the next 5 years. Based on this information, a small number of people will be contacted at a later date and asked if they would be prepared to take part in an interview about their symptoms.

The study will not affect any referrals or treatment you get from the GP in any way. So if your GP wishes to refer you to a specialist of any kind, this will happen in the usual way – the study will not affect his or her decision-making at all.

What are the advantages and disadvantages of taking part?

Although there will be no direct benefit for you, we hope the information gained from the study will be used to improve early detection of cancer in the UK. The main disadvantage is having a blood sample taken. This can in some cases cause a small local bruise that will disappear in a few days' time.

What will happen to the samples?

The blood and saliva samples will be sent to the University of Southampton, Faculty of Medicine. A full blood count will be carried out and the remaining blood and any saliva samples will be stored in freezers in the Human Tissue Bank until funding can be secured to carry out further tests on them which will include looking at genes (DNA) and protein markers in relation to any cancer diagnosis that may occur in the future. No other genetic analysis will be done.

Will my taking part in the study remain confidential?

All information collected from you will be held in accordance with the Data Protection Act 1998; signed consent forms will be stored in locked filing cabinets until the end of the study after which they will be stored and then destroyed in accordance with Southampton University regulations. The information you provide on the Internet will be held on a password-protected secure server. Your GP will be aware of your participation. The results, which will not identify you, may be shared with other doctors and researchers. If you withdraw from the study any information already collected would be held until the end of the study when it would be destroyed; it would not be used in the analysis of any results.

What happens if I change my mind?

It is up to you to decide to join the study. You are free to withdraw at any time, without giving a reason. This would not affect the standard of care you receive

What happens if something goes wrong?

It is unlikely that anything will go wrong as we are primarily only looking at information about you provided by yourself or your GP. However, if you have any concerns or feel that you have been placed at risk you can contact your local co-ordinating centre *<insert details>*. Alternatively, you may contact your local Patient Advisory Liaison Service (PALS) *<insert local PALS information for each centre>*. If you remain unhappy and wish to complain formally you can do this through the NHS complaints procedure.

Your doctor will treat you in exactly the same way as he/she would if you were not in the research.

What will happen to the results of the research study?

The results will be shared with the medical community at meetings and will be published in medical journals. The results will also be used on the National Institute for Health Research website. A summary of the findings will be sent to all the people taking part that would like to see the results, and the full report can be made available on request.

Where can I get more information?

If you would like to take part in the study or if you have any further questions please do not hesitate to get in touch with Sue Broomfield using the contact details below.

Contact details of the Researcher:

Name: Sue Broomfield

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THANK YOU FOR TAKING THE TIME TO READ THIS INFORMATION