What is the study about?

The Birmingham COPD Cohort Study is a medical research study that will include over 2000 people with a lung problem called chronic obstructive pulmonary disease (COPD) also known as emphysema or chronic bronchitis. We will also include some people with similar lung symptoms who may not have COPD. The study will initially run for 3 years and is designed to identify the best methods for forecasting the severity and course of the disease so that we will identify factors that allow earlier and improved treatment.

Why is the study being done?

COPD is an increasingly important lung problem, leading to increasing breathlessness and sometimes other health problems. It affects about 1 in 20 people in the population, and as the condition progresses some people have periods when their breathing gets worse and need to be in hospital. These periods (exacerbations) can become more frequent over time. Unfortunately we don't fully understand why some people are more prone to these exacerbations and what factors contribute to the disease progressing.

By identifying these factors we may be able to develop new treatments that alter the course of the disease at an early stage and improve the outcome for those with COPD. We think that this is an important study and your help would be greatly appreciated.

What if I do not want to take part?

You are under no obligation to take part in this study; your medical care will not be affected in any way. If you do not want to take part, please fill in the reply slip to say so and return it in the addressed pre-paid envelope provided, as soon as possible.

What will I have to do if I choose to take part?

The first stage is to return the reply slip or contact us and we will schedule an appointment at your GP practice or other convenient place for our researchers to do a study assessment. You will be asked to complete a questionnaire and bring some information with you for your first assessment. There will only be one other assessment approximately 3 years later. In between you will be asked to fill out a few questionnaires by post.

What happens during the study assessment visit?

The appointment at your first assessment should take approximately 2.5 hours. During the visit we will collect information on, or measure:

1. Your lung health by simple blowing tests that measure the air you blow out (how much air and how fast), before and after breathing a common medicine (Salbutamol) given by an inhaler.
2. A questionnaire about your respiratory health, general health, work, and family life style.
3. Information from your GP notes on your medications and other medical details, which will be confidential.
4. Other general measurements, such as your height, weight, body fat, blood pressure, waist and neck circumference and length of your arms.
5. Sit to stand test; this test takes about 10 minutes, and will involve counting how many times you can stand up and sit down in a chair, in one minute.
6. Muscle strength test (grip strength); this involves squeezing a device once with each hand.
7. In addition we would like to collect a blood sample of the equivalent of about 2 tablespoons from a vein. This will be entirely voluntary. The blood sample will be kept for long term storage for future studies to assess markers in the blood which influence lung disease. If you do not want to give a blood sample you can still take part in the rest of the study. Any future tests on this blood would be subject to the permission from an ethics committee.

The baseline assessment should take about two and a half hours to complete. The second assessment visit will be done about 3 years later; we will contact you to

schedule an appointment at your GP practice surgery or other convenient place for this assessment. This second visit is similar to the baseline visit, but we will not take any blood.

Between the baseline assessment and the 3 year assessment we will send you a questionnaire about your respiratory health, general health and life style, with a postage-paid return envelope around every 6 months until the final assessment at end of the study (year 3). If you are in work, we may also ask you to keep a short daily diary to note your health each day and any days when you miss work. As part of our standard quality assurance we may also occasionally need to contact you to confirm the data you have provided.

Finally, you may be invited to participate in a focus group to discuss your perceptions and experiences related to this research – this is completely voluntary.

We may contact you in the future about participating in other research studies.

What happens at the end of the three years of study?

To fully understand the course of COPD and related lung problems and the influences on long term outcomes, we need to continue to monitor all those participating in the study beyond the initial three years. At the end of the three years you may be invited to participate in other research studies and assessments with your permission. This will be entirely optional.

However, we would like to follow up the health of everyone who agrees to take part directly through their medical and other health related records. All such information will be held in strict confidence with careful controls and no identifiable information on participants would be available to anyone outside the BLISS study team. However we hope you would find your participation a rewarding experience and of course any costs you incur for travelling will be reimbursed.

What are the possible disadvantages and risks of taking part?

Disadvantages of taking part are time and travel: you will be asked to attend for study assessments twice over the 3 year period and fill in a postal questionnaire every 6 months. If you choose to take part in the study then there is a small chance we may detect an abnormality in your test results (e.g. blood pressure), that requires treatment. With your agreement we will pass these details onto your GP for further consideration. These are generally good things to be aware of as you may benefit from treatment.

It is possible that you may be slightly uncomfortable with some of the questions or measurements. If that is the case, you will have the option of skipping such questions or measures. You may also feel some discomfort when you have blood taken, but all our staff are specially trained to minimise any discomfort.

What are the possible benefits of taking part?

The information that we get from this study will help us to understand more about COPD and possibly improve future treatment. If you participate in the study, you will have better monitoring of your lung health and other aspects of your health. Finally, you will have the opportunity to help develop new tests for the future.

What do I need to do now?

First of all, we ask if you would read this patient information letter thoroughly and decide whether you would like to participate or not. Then please return the reply slip in the pre-paid envelope provided, as soon as possible. There is no need for you to add a stamp.

What if I have more questions or do not understand something?

If you have more questions, or you do not understand something in this information letter, please contact our study team (details below). Alternatively, you can speak with your GP. If you would like independent advice on participating in research studies, you can contact the Patient Advice and Liaison Service (PALS) at Queen Elizabeth Hospital Birmingham (0121 371 3280, PALS@uhb.nhs.uk).

What happens now if I decide to take part?

Once we receive your reply, we will contact you to schedule the study baseline assessment.

What happens if I change my mind during the study?

You can withdraw from the study at any time without any pressure and it will not affect your usual care from your GP in any way. If you decide to withdraw, please contact the study team (details below).

Do I need to agree to everything in the study?

No. If you feel uncomfortable with answering certain questions or do not want to have certain measures or to give a blood sample, you do not have to do so. You can still participate in the other parts of the study.

Will my taking part in the study be kept confidential?

All your personal identifying information (such as name and address) will be kept separately from other health and medical information we have for you. No one outside the study team can access your personal information. However, if you consent to take part in the research any of your medical records may be audited by people from regulatory authorities to check the study is being carried out correctly. Apart from these study activities, your name will not be disclosed outside the hospital/GP surgery. Your GP will be notified of your participation in the study. All data will be held on secure computers that block unauthorised access (e.g. by hackers) and are password protected.

Who is running the study?

This study is a joint study between the University of Birmingham, Queen Elizabeth Hospital and South Birmingham Primary Care Trust, with the cooperation of your GP. It is funded by the UK National Institute for Health Research through the Department of Health and has been approved by the West Midlands (Solihull) Research Ethics Committee.

What happens to the results of the research study?

Once we have analysed the results we will publish them in a paper in a medical journal. We will also publish our results on our website. You will not be identified in any publication.

Any queries or further information please contact:

Miss Ellen Sainsbury, BLISS Study administrator

Public Health, Epidemiology and Biostatistics

University of Birmingham, Edgbaston,

Birmingham, B15 2TT

T: 0121 414 8348 bliss@contacts.bham.ac.uk

Website: http://www.haps.bham.ac.uk/publichealth/research/bliss.shtml

Thank you for taking the time to read this