

Participant Information Sheet (PIS): Interview phase

REC Protocol Number: 16/LO/1696

Safe withdrawal of inhaled steroids in mild or moderate COPD (SWAP Study)

We are inviting you to take part in a research interview as part of our study of the prescribing of inhaled steroids in mild and moderate COPD. We want to find out if it is acceptable to participants to stop inhaled steroids where their usefulness and safety is uncertain. We would like you to talk to a researcher to discuss your inhalers. We will ask for your views of COPD and its treatment. **We will not ask you to stop using your inhaled steroid or make any changes to your treatment.** This study is funded by the NHS through the National Institute of Health Research. It is based in general practices in London and is being run by King's College London. It has the support of Guy's and St Thomas' NHS Foundation Trust.

What is the purpose of the study?

There is uncertainty about the usefulness and safety of inhaled steroids in mild and moderate COPD. A small number of people may develop side effects from these drugs. We want to understand better how people with mild or moderate COPD would feel about stopping these inhalers. Your views will help us to plan a larger study to see if inhaled steroids can be stopped in people with mild or moderate COPD. We will not ask you to take part in the larger study.

Why are we investigating the withdrawal of inhaled steroids in people with mild or moderate COPD?

High dose inhaled steroids are widely prescribed to people with mild or moderate COPD. For most people with mild or moderate COPD there is no evidence of any benefit from these drugs. They increase the risk to people of developing pneumonia. There are about 3000 cases of pneumonia each year in England as a result. There is also a small increased risk of bone fractures and cataracts. These side effects can be dangerous. The drugs are also costly to the NHS. In the NHS in England an estimated £122 million is spent each year in prescribing inhaled steroids to patients with mild and moderate COPD. Little is known about patients' feelings towards these drugs or towards the suggestion of stopping them. We are interested in your opinion about this.

How will this research work?

We will recruit up to 30 participants with mild or moderate COPD who have used inhaled steroids for at least three months. Participants will be recruited from general practices in London.

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What will taking part involve for you?

Your general practice has invited you to be interviewed for this study. An appointment will be arranged for you at a place of your choice, for example your home address or GP's surgery. This appointment will be with a researcher from the project team. The appointment will last for approximately 60 minutes. We would like you not to use your inhalers on the morning of your interview so we can do a test of your breathing. Please bring your blue inhaler (salbutamol) to the interview. The breathing test is called spirometry. This will tell us how severe your COPD is. The researcher will ask you about your understanding of COPD, about your use of inhaled steroids, and how you would feel about being asked to stop the drug. What are the advantages or disadvantages you feel from using the inhaled steroid? Do you have any concerns about the effect of stopping the drug on your symptoms and quality of life? We will not ask you to stop the inhaled steroid or suggest any changes to your treatment. The researcher will record the interview so that it can be typed up later. This helps to make sure we have a record of everything you say.

Will my taking part in this study be kept confidential?

The recordings and transcripts of the interviews will remain strictly confidential at all times. We will take steps to protect your personal information and will not include your name on any forms, reports or publications. Anonymised data may be shared with other researchers and clinicians. All data will be stored securely by King's College London for 7 years, after which it will be destroyed.

What are the benefits of taking part?

Your contribution will be very useful in helping us to design a larger study into the acceptability of stopping inhaled steroids in people with mild or moderate COPD.

Who has reviewed this study?

This study has been funded by the NHS National Institute of Health Research. It has been assessed by independent researchers as safe for patients and having important benefits for patients. This study has been reviewed and received a favourable opinion from the London-London Bridge Research Ethics Committee.

What are the possible disadvantages or risks of taking part?

The assessment will take approximately 60 minutes. We do not think that there are any risks involved with taking part in this research. If you are unhappy with any aspect of this research you will be able to speak with the researcher on the telephone or meet the researcher in person if you prefer. We will give you a £20 shopping voucher as reimbursement for the time it takes for you to help with this project.

What will happen if I decide to withdraw from the research?

You will be able to withdraw from the interview at any time without explaining why. If you withdraw from the study it will have no effect on your treatment. If you agree to participate in the study then your general practitioner will be informed.

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 Dr. Gill Gilworth Trial Manager, Tel 0207 8486957, Mob: 0790 111 0601, gill.gilworth@kcl.ac.uk; Tim Harries NIHR Doctoral Research Fellow, King's College London, Tel: 0207 848 8675 or Dr Patrick White, 02078488679, patrick.white@kcl.ac.uk. If you remain unhappy and wish to complain formally, you can do this through the GP surgery and also through the Guy's and St Thomas' Patients Advice and Liaison Service (PALS) on 020 7188 8801, pals@gstt.nhs.uk. The PALS team are based in the main entrance on the ground floor at St Thomas' Hospital and on the ground floor at Guy's Hospital in the Tower Wing. In the event that something does go wrong and you are harmed during the research you may have grounds for legal action for compensation against Guy's and St Thomas' NHS Foundation Trust and/or King's College London but you may have to pay your legal costs. The normal National Health Service complaints mechanisms will still be available to you (if appropriate). If you have any concerns about how your treatment is affecting you please discuss these with your GP.

Further information and contact details

Once the study has finished if you would like to receive written information on the findings of the study then please ask the researcher at your appointment.

If you want any further information or need to contact the research team for any reason please phone or email or write to Dr Gill Gilworth or Dr Patrick White who is the chief investigator (contact details below).

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