

*We are inviting you to take part in the OSAC trial and would be grateful for your help with our research.*

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*Participation in the trial is entirely up to you and you can withdraw at any time, without having to give a reason, and without any effect on your medical care*

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*Before you decide, please read this leaflet which explains why we are doing this research and what we are asking people to do to help us.*

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*Please take time to read it carefully, and talk about it with your family, friends, and GP if you wish.*

*Please ask your doctor or nurse if there is anything that is not clear.*

#### WHAT ARE THE BENEFITS FOR ME?

The NHS has approved the trial because the balance of evidence suggests the treatment has a good chance of working. We do not know if there will be an immediate benefit for you in taking part in this trial, but you will be contributing to research that improves future treatment and helps the NHS to run more efficiently. To thank you for your time in helping us, we will give you £15 worth of High Street vouchers to spend on anything you like: £5 when you sign up, £5 when you've completed the first two weeks of the symptom diary and another £5 when you finish the diary.

#### WHAT IF I DON'T WANT TO CARRY ON?

You can leave the trial at any time. Although we'd like to know why, you do not have to give us any reason. With your permission, we would only use the information we have already collected up until that point. Your medical care will remain exactly as before.

#### IF I WANT TO KNOW MORE?

If you would like to find out more information about the trial please talk to your doctor or nurse.



# COUGHING?

Are you aged 18 and over?

If your answer is yes,  
you may be able to help with the  
**Oral Steroids for Acute Cough** trial.

PATIENT  
INFORMATION  
LEAFLET

## WHAT IS THE OSAC TRIAL?

Coughs caused by chest infections can be a real nuisance. Cough mixtures don't work, and antibiotics are proven to be unhelpful for most sufferers. Researchers at the University of Bristol want to find out whether a short course of steroid tablets could help people with a chest infection feel better more quickly. If we show that steroids can help people with chest infections, doctors will have a better treatment to offer their patients, the NHS can save money and reduce antibiotic prescribing to help prevent the spread of hospital infections such as MRSA.

## WHAT ARE STEROIDS AND ARE THEY SAFE?

Steroids (cortisone or corticosteroids) are used in medicine to reduce inflammation (the swelling of body tissues as part of the immune response to an illness) and are very different to the 'anabolic' steroids used by some athletes and bodybuilders. We are testing an approved medicine called prednisolone, which is widely used in the UK to treat asthma and other conditions. We know that a short course of prednisolone at the dosage that we are testing in this trial is safe for eligible patients, and that most people will not get any side effects. The following information is from an NHS leaflet about steroid tablets ([www.patient.co.uk](http://www.patient.co.uk)): "A short course of steroids usually causes no side-effects. For example, a 1-2 week course is often prescribed to ease a severe attack of asthma. This is usually taken without any problems. Side-effects are more likely to occur if you take a long course of steroids (more than 2-3 months), or if you take short courses repeatedly."

We have good reason to believe that prednisolone could help people with chest infections to feel better more quickly.

## HOW DOES A 'TRIAL' OF STEROIDS WORK?

A trial like OSAC is an approved scientific method involving real patients. Some patients are given the trial medicine (in this case, tablets containing prednisolone), and others are given a placebo (tablets which look and taste exactly the same but which do not contain any medicine). The researchers then compare the time it takes for the people in both groups to feel better.

## CAN I HELP AND WHAT WOULD I HAVE TO DO?

If you are seeing your GP for a cough that has lasted no more than 28 days you may be able to help us with this research by agreeing to the following:

- a routine appointment with your doctor/nurse - they will treat your chest infection in the normal manner before checking if you are eligible for the trial;
- a 2nd longer appointment with the same or a different doctor/nurse on the same day or the next working day – a chance to ask questions, sign consent form, have a more detailed physical examination (**NO blood tests are involved**) and be given a Trial Patient Pack to take home;
- take the trial medicine for 5 days;
- complete a symptom diary every day (on-line or on paper) for up to 28 days or until you have been symptom-free for 2 days running – this should take about 5 minutes each day (if your cough lasts more than 28 days we will phone you weekly to ask about your symptoms but you will not need to fill-in the symptom diary);
- receive weekly phone calls from the trial team

to answer 4 sets of questions about your overall health, use of NHS services and your expenses – these calls should take about 15 minutes;

- a review of your GP medical records 3 months after you join the trial (you do not need to be present).

## WHY DO I HAVE TO COMPLETE THE DIARY FOR 28 DAYS?

For most people a bad cough will clear up within 3-4 weeks. We ask all patients to give us 28 days worth of information to make sure that our data represents the whole recovery process for most people. We know this is a big commitment to ask of you, but it will ensure that the data we collect is of the highest value to this research.

## WILL IT AFFECT MY REGULAR MEDICATION?

No. If your current medication affects your ability to participate in this trial, your doctor will advise you.

## WHAT'S THE DOWNSIDE?

- First, we believe that Prednisolone could help you to feel better and we do know that it's safe, but it is not yet clinically proven for the treatment of coughs and chest infections.
- Second, you would be giving us your valuable time to complete the daily symptom diary and receive weekly phone calls from us for 4 weeks. So, if you might be away on holiday, or otherwise unavailable to be contacted, you might not be able to take part.