



NEWSLETTER

ISSUE 2

OCTOBER 2013

THE GOAL

436 patients across the whole trial, of whom at least **350** go on to complete their Symptom Diaries.

Our first **FOUR** recruiting GP practices have recruited **9** patients so far, of whom the trial team has been able to follow up **7**, and one has been withdrawn.

Only **427** recruits to go!
(Really we just want 343 more perfect patients, but while we try to be optimistic we know this may not happen).

OSAC IS GETTING GOING

It's taken time to get this trial in motion, but we now know that OSAC works. The first sites have shown that patient recruitment is not only feasible but facilitated by the highly organised recruitment materials, and we know that patients are content and able to complete the symptom diary. We are confident that with your support it will be possible to recruit enough patients to make OSAC an influential study that will either open up a raft of new research into the role of steroids for lower respiratory tract infection or demonstrate their lack of effectiveness for this condition. We have one winter season to recruit, so let us help you to get OSAC working in your practice.

POP THE QUESTION...

Early indications suggest that once a patient is asked whether they would like to participate in OSAC, the pathway is relatively smooth from there. Patients always have the option of declining, but only 4 of the patients screened so far have said no: two did not wish to participate in any trial, one did not wish to participate in a trial of steroids, and one felt too unwell. Those patients who have agreed to take part appear to have had positive experiences of completing the symptom diary.



NEW SITES

The Bristol trial team is delighted to now have 15 GP practices on board, of whom four have taken the plunge into starting recruitment: Elm Tree Surgery, Shrivvenham; Oldfield Surgery, Bath; Rowden Surgery, Chippenham and Frome Medical Centre. We're very excited to have so many experienced practices waiting in the wings and ready to get going.

In particular, welcome to our very new sites Bradgate Surgery, Bristol; The Health Centre, Bradford on Avon; Vine Surgery, Street; The Beehive and St Michael's Surgeries and St James's Surgery in Bath; Chew Medical Practice, Batheaston Medical Centre and Churchdown Surgery in Gloucester. We're working hard to get our final sites on board and looking forward to training the first few Devon GP practices soon.

SAME DAY vs NEXT DAY RECRUITMENT

Many practices have asked us whether it is possible for patients to return to the practice on the day after they have seen the GP, for their recruitment interview.

At present this is against the protocol, but we are submitting a protocol amendment to enable next day recruitment. Unfortunately these things take time, so it will be another few weeks before we hear about that. I will let all practices know directly once the amendment has been approved.



KEEP CALM
AND
COME BACK
TOMORROW

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NEWSLETTER

YOUR QUESTIONS...

The OSAC eligibility criteria have prompted a great number of questions from primary care clinicians planning to recruit to OSAC. These questions have been very informative for the trial team and we would like to share them with our recruiting sites. Here is a selection:

Q. Why is the list of exclusion criteria so extensive? Why exclude people on the basis of osteoporosis, or recent exposure to herpes zoster if they have not previously had chickenpox?

A. Many of the exclusion criteria, especially the list A-P on p2 of CRF1 (face-to-face eligibility assessment) refer to conditions which are made worse by exposure to steroids, e.g. osteoporosis, epilepsy, ocular herpes simplex, and chickenpox. Because we are testing a relatively high dose in OSAC, it is necessary to exclude all patients with such conditions, to ensure patient safety. (Remember even if the results of the OSAC trial turn out to be positive, we will NOT be advocating 40mg prednisolone for 5 days as an appropriate treatment option.)

Q. What about undiagnosed COPD? Some asthma studies exclude patients with a 10 year pack history as they possibly have a degree of COPD.

Why not exclude them from OSAC?

A. If you *strongly* suspect COPD clinically, then we suggest excluding such patients, but a 10 year pack history on its own is not sufficiently sensitive and specific to diagnose COPD. We will be reviewing patients' medical records 3 months after trial participation so we can ascertain any in whom you subsequently diagnose COPD (and asthma) to see if excluding them from the analyses makes a difference to our estimates of the treatment effects.

Q. Should I recruit the 60 year old smoker who presents with an acute cough of three weeks duration in whom I suspect lung cancer?

A. Yes. We definitely want to include these patients. GPs should continue to investigate for lung cancer as per usual practice / DoH guidelines. If the patient receives a diagnosis of lung cancer within the trial period (3 months from recruitment), this may need to be reported to the trial team as a Serious Adverse Event (SAE), depending on the specific details of the diagnosis, i.e. if it meets the criteria defining an SAE, and patients should not be routinely withdrawn.

Q. Wheeze is one of the four presenting symptoms indicating potential eligibility. Is wheeze not primarily an indication of asthma?

A. Wheeze, cough and shortness of breath are hallmark symptoms of asthma, but also frequently occur in patients with acute chest infections, especially during outbreaks of so-called 'atypical' infections such as those due to *Mycoplasma pneumonia* and *Chlamydia pneumonia*. We therefore wish to include patients with these symptoms in the OSAC trial, but we will review patients' medical records 3 months after trial participation so we can ascertain any in whom you subse-

quently diagnose asthma (and COPD) to see if excluding them from the analyses makes any difference to our estimates of the treatment effects.

Q. If a patient has recently had antibiotics for a cough but comes back after their course of antibiotics still complaining of a cough, can they then be included in OSAC?

A. Yes. Exclusion criterion 1.2.4 (CRF1) specifies that the patient must be excluded if he or she "requires an antibiotic today to treat another infection unrelated to their acute cough, e.g. a co-existing cellulitis". This criterion applies equally to a course of antibiotic medication that may have been prescribed previously for the acute cough. As long as the patient has finished the course of antibiotics before today, i.e. completed the course on a previous day up to the day before, or has otherwise stopped taking them, and the patient does not require an antibiotic on the same day for the cough or for any other purpose, they may be included in OSAC.

Q. The 'asthma' exclusion criterion states that patients should be excluded if they have received asthma medication, such as an inhaled bronchodilator (Salbutamol) within the past 5 years. Does this exclude non-asthmatic patients who may have been prescribed inhaled bronchodilators for the symptoms of a chest infection?

A. Non-asthmatic patients are not excluded if they have been prescribed inhaled bronchodilators for chest infection. But if a patient has a history of asthma, and has been treated with inhaled bronchodilators for asthma symptoms, they are not eligible to take part.

Q. What if there's a 'flu epidemic and most patients presenting with a cough also have the 'flu' (if there's large numbers of people with flu, might that skew things a bit)?

A. In the original research proposal, we were keen to include bacteriology and virology in this study so that we could understand the mix of microbes that will be circulating in the winter of 2013-14. Unfortunately, the funder would not agree to support this aspect of the trial. If there is a 'flu epidemic, we recognise this may have an effect on the results as we will be recruiting more patients with a cough due to having the 'flu. We will, however, consult routinely available data in order to understand the generalizability of the results.

Great minds...

If we knew what we were doing, it would not be called research, would it?
Albert Einstein

Research is creating new knowledge.
Neil Armstrong



NEXT MONTH:

- Our interview with the Chief Investigator
- More recruitment feedback
- A really bad joke