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OSAC (ORAL STEROIDS FOR ACUTE COUGH) TRIAL

NEWSLETTER

ISSUE 7 February 2014

YOU HAVE RECRUITED 122 WONDERFUL[1] PATIENTS!

We are delighted and impressed that so many practices have started recruiting for OSAC—the timeline shows who has come on board.

[1]Ok, to be more precise, 95% are wonderful.

BUT WE STILL NEED MORE PUFF!

For OSAC to be successful this season, we just need a few more of our 59 fully set up sites to start recruiting patients.

AND MOST PATIENTS SAY YES...

OSAC screening data show that, on average, 2 out of 3 patients who are invited to be screened agree. Of those screened, only 15% are subsequently excluded because of ineligibility. So the current ***screening to recruitment rate is around 2:1,*** *much better than our initial estimates of 9:1.*

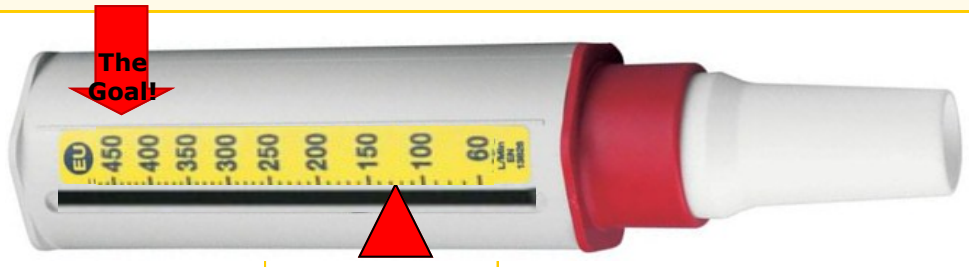
Of those patients who decline to take part, about one third say no because they do not want to be in a trial of steroids, or indeed any trial at all, and others are mostly prevented by time constraints.

WHY RECRUIT TO THIS TRIAL?

What's in it for patients?
They get to talk to our lovely Research Nurse Sue, and they receive £15 in thank you vouchers. Most importantly, **they may feel better sooner.**

What's in it for you?
Being fantastic, adding real value to NHS funded research by helping to answer a question worth many £millions to the NHS and making 1 patient (maybe) and several statisticians very happy.

What's in it for your practice?
£315 in revenue, per patient.



GP Practice start-up timeline

32 — February
- Rolle Medical Practice
- Burnley Wood Medical Centre
- Windrush Medical Centre

29 — January
- Wellspring Surgery
- Sherbourne Medical Centre
- Burbury Medical Centre
- Oakley and Overton Surgery
- Batheaston Medical Centre
- Eynsham Medical Centre
- Oakenhurst Medical Practice
- The Avenue Surgery
- Homewell Practice
- Brockway Medical Centre

19 — December
- Rosebank Medical Practice
- Churchdown Surgery
- Sedbergh Medical Practice
- Richmond House Surgery
- Queen Square Medical Practice
- Bradford on Avon Health Ctr

13 — November
- Yorkleigh Surgery
- Portland and Hatherley
- Westlake Surgery
- Osborne Practice
- Forest End Surgery

8 — October
- Chew Medical Practice
- Three Swans Surgery
- Bradgate Surgery
- The Village Practice

4 — September
- Oldfield Surgery
- Elm Tree Surgery

2 — August
- Frome Medical Practice

1 — July
- Rowden Surgery

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Your Practitioner Insurance Policy* (PIP) for Recruiting Younger (25 or under) Patients to OSAC

What's in it for you? 100% cover— 100% of the time

What's in it for us? 100% primary outcome data!

If there were any money involved there would be a

Total Money Back Guarantee!!

As you are aware, the success of OSAC depends on our being able to follow up patients, who make a big commitment: to take the trial tablets, to do a daily symptom diary for at least a week and as long as they feel unwell after that, and to receive four weekly phone calls from Sue, the OSAC Research Nurse.

And as you also know, consent—time-consuming as it may be— is the foundation of any ethical research. It's also your own **Professional Insurance Policy (PIP)**, the best way to ensure that patients have control over whether or not to enrol in clinical trials such as OSAC. The bottom line is that effectively obtaining consent protects us from serious allegations such professional negligence, even personal trespass.

We've found that, although most patients have willingly complied and provided extremely valuable data for the trial, a number of younger patients have proved difficult to follow up, and do not respond to our phone calls and texts. Sometimes this is because they have an extremely busy or hectic lifestyle - for example, a young single mum - and in these cases we do our best to be flexible and to fit in. Occasionally, however, it becomes clear that the patient is not very comfortable with one or more aspects of taking part, such as taking the trial medicines, or receiving phone calls on their mobile.

So here are our top tips for ensuring that, when inviting all patients and particularly younger ones, your PIP Policy is 100% valid, and we get 100% commitment:

1) Give sufficient information and don't blind them with science. Explain what a clinical trial is, why research is important, and the potential value of their contribution to the NHS and to people like themselves in the future;
2) Direct simple questions about the trial to the patient, to check they fully understand what they are agreeing to;
3) Make sure they are OK to receive phone calls from a Bristol University Research Nurse: you can ask the patient to key Sue's phone number, **0117 331 4513**, into their phone at recruitment, so they won't be alarmed by any mysterious callers;
4) Always allow sufficient time for the patient to decide whether or not to take part;
5) Last but not least, because **some young people need more time to be assertive**: it really is okay to say No. 'No thanks', is nicer, but just 'No' will do.

And Remember! Patients who feel obligated to consent should probably be considered to have failed the consent procedure.

THREE (and a half) GOLDEN RULES

1. Patients should take the first dose of their trial medication **on the same day that they are recruited**, not wait for the next morning.
2. Please explain to patients how to complete the first part of the symptom diary (Day 1 questions, and Week 1)
3. Please ensure that patients are happy to be telephoned by Sue Harris, the Trial Research Nurse

3½. Please ask patients to provide a second contact telephone number, and ideally an email address as well.

FROM US TO YOU

To express our appreciation of GP practices' efforts in recruiting patients, the OSAC investigators will be sending those practices who recruit ten patients a mystery prize, which will hopefully enhance coffee breaks for the whole practice team.

Furthermore, we will be sending a prize to the practice that recruits the 125th, 150th, 175th (and so on) patient. We will also award ad-hoc prizes for recruitment, because life is too short not to.

WHAT IF MY PATIENT GETS WORSE?

If a patient that you've recruited to OSAC returns to the surgery within the first week because their condition deteriorates, and further medicines are prescribed (including antibiotics or steroids) **and** you advise the patient to stop taking the trial medicine, this does NOT mean they should be withdrawn from the trial or send their symptom diary back. As long as they are willing, we would really like them to continue in the trial so we can understand how long it takes for them to feel better: this is one of our primary outcomes.

Please can all OSAC recruiters make your colleagues aware of this, as we know that patients may be seen by other practice clinicians who are not involved with trial recruitment. NB: Unblinding of the trial medicine should only be used in an emergency situation when the clinician feels the patient's condition is serious enough that this is warranted.

HANDS UP WHO WANTS TO WITHHOLD ANTIBIOTIC TREATMENT FROM A PATIENT WITH A CHEST INFECTION WHO SUBSEQUENTLY DETERIORATES? We thought not, but...

The following text is paraphrased and extracted from the editorial in the British Journal of General Practice (BJGP) by Professor Alastair Hay:

You may say, "But my patient is special and needs antibiotics because they are (i) a smoker / (ii) have green phlegm / (iii) a more severe illness / (iv) chronic lung disease / (v) are going on a family holiday tomorrow / (vi) have a vitally important business meeting in Washington DC next week [delete as appropriate]."

A new paper published this month, by an international group of researchers leading the way towards improved antibiotic treatment decision making, looks at whether antibiotics may offer extra benefits (or harms) to patients who might be considered "special". They analysed the effects of antibiotics on patient subgroups defined by the presence or absence of factors that are of clinical concern, such as options (i) to (iv) above.

Although there were some important findings, suggesting that patients with significant past medical histories, shorter prior illness duration and those who don't smoke gain from being prescribed amoxicillin, the researchers conclude that ***"There is no clear evidence of clinically meaningful benefit from antibiotics in subgroups of patients with uncomplicated LRTI".***

The main trial article, published in *Lancet Infectious Diseases*, was the largest of its kind. 2061 patients were randomised to amoxicillin 1g or placebo three times daily and asked to complete a diary to measure duration and severity of the most common LRTI symptoms. Symptom severity was measured using a scale of zero ('no problem') to six ('as bad as it could be') that included the interim score, three ('moderately bad'). Despite the higher than standard UK treatment dose, the trial demonstrated no difference in overall duration of all symptoms rated 'moderately bad' or worse (≥3) or their severity at days 2 to 4. Although new or worsening symptoms occurred slightly less frequently in the amoxicillin group (16% vs. 19%, NNT 30), nausea, diarrhoea or rash occurred more frequently (NNH 23) and there was one anaphylaxis in the amoxicillin group. Three (0.15%) patients needed hospitalisation for cardiovascular or respiratory problems, two in the placebo and one in the amoxicillin group.

To summarise, the main trial suggests patient safety was not improved by using antibiotics—if anything, their use may compromise safety—more patients experienced side effects than were prevented from experiencing worsening of their illness, and we already know about the dangers of anaphylaxis and antimicrobial resistance.

You can find the full article in the BJGP at http://bjgp.org/content/64/619/e75 and the editorial on pages 60-61 of the February issue.

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