



Oral Steroids for Acute Cough Trial: ELIGIBILITY CHECKLIST

Inclusion (ALL of the following):

- ✓ Aged 18 years or over
- ✓ Consulting for acute (≤ 28 days) cough as main presenting symptom
- ✓ In past 24 hours, patient has had at least one of the screening symptoms (a-d) suggestive of acute LRTI:
 - a. phlegm (sputum)
 - b. chest pain
 - c. shortness of breath
 - d. wheeze
- ✓ Patient and practice have sufficient time for consent and randomisation into trial by end of today
- ✓ Patient able and willing to give informed consent themselves
- ✓ Patient able and willing to complete the daily symptom diary themselves
- ✓ Patient able, willing and available to receive weekly follow-up telephone calls from the trial team

Exclusion (ANY of the following):

- X Is unable to give informed consent or complete the trial paperwork (including the symptom diary) through mental incapacity, e.g. major current psychiatric illness, learning difficulties and dementia
- X Known lung cancer or chronic lung disease
- X 'Active' diagnosis of asthma (has received any asthma medication in past 5 years)
- X Previously entered in the OSAC trial
- X Known immune-deficiency, e.g. chemotherapy causing immunosuppression, asplenia or splenic dysfunction, advanced cancer or HIV infection
- X Patient's RTI warrants same day hospital admission or immediate antibiotics (NB giving a delayed prescription does not exclude):

NICE guidelines: patient warrants immediate antibiotic treatment if ONE OR MORE of the following is true:

- X Clinically very unwell or has symptoms and signs suggestive of pneumonia, e.g. tachypnoea (>20 bpm), unilateral chest signs or consolidation, or hypoxia (oxygen saturation $<94\%$) or other systemic infection, e.g. suspected bacteraemia OR
- X At high risk of complications, including patients with chronic heart, chronic lung (e.g. COPD, bronchiectasis and cystic fibrosis), chronic renal, chronic liver or neuromuscular disease or immunosuppression; or with complications from previous episodes of lower respiratory tract infection, e.g. hospital admission for pneumonia OR
- X AGED OVER 65 years with at least TWO of the following criteria, or AGED OVER 80 years with at least ONE of the following criteria:
 - I. Unplanned hospitalisation within the previous year
 - II. Type 1 or Type 2 diabetes
 - III. History of cardiac failure

- X Requires an antibiotic today to treat another infection unrelated to their acute cough, e.g. a co-existing cellulitis

Exclusion continued (ANY of the following):

- X Recently (≤ 1 month) used inhaled corticosteroids
- X Recently (≤ 1 month) used short (≤ 2 weeks) course systemic corticosteroids
- X Currently using, or has previously (≤ 12 months) used, systemic steroids for a cumulative period >2 weeks, i.e. "long-term" use
- X Known to be pregnant, trying to conceive or at risk of pregnancy (e.g. unwilling to take a reliable form of contraception) in next month, or lactating
- X This is not patient's usual practice, i.e. patient is visiting or not intending to stay with practice for the 3 month trial follow up period
- X Has been involved in another medicinal trial within the last 90 days or any other clinical research study within the last 30 days
- X Is unable to swallow tablets
- X (For winter 2013/2014 only) patient is aged 70 or 79 and due to receive the shingles vaccine in conjunction with the influenza vaccine

Has any of the following (A-P) known contra-indications or cautions to oral steroids:

Current OR previous history of:

- X A. Peptic ulcer disease
- X B. Osteoporosis
- X C. Previous TB
- X D. Glaucoma
- X E. No previous chickenpox AND known recent (≤ 28 days) history of close personal contact with chickenpox OR herpes zoster
- X F. Suspected ocular herpes simplex
- X G. Known allergy to prednisolone or other OSAC trial tablet ingredients (potato starch, lactose monohydrate, colloidal silicon dioxide, sodium starch glycolate, magnesium stearate), galactose intolerance, Lapp lactase deficiency or glucose-galactose malabsorption
- X H. Cushing's disease
- X I. Epilepsy
- X J. Severe disorders, e.g. manic depression, previous steroid psychosis
- X K. Previous steroid myopathy
- X L. Intends to use a live vaccine in the next 8 weeks OR has received a live vaccine in the previous 2 weeks (NB: assess vaccine status by checking BNF)

Current history only:

- X M. Uncontrolled diabetes (HbA1C $> 8\%$)
- X N. Any other interacting medication, e.g. phenytoin and anti-coagulants
- X O. Uncontrolled hypertension (NB: as per Responsible Clinician's routine clinical judgement)
- X P. ANY other BNF listed contra-indication or caution (as per Responsible Clinician's routine clinical judgement)
- X Significant interactions with the patient's existing medication identified

FOR ALL PATIENTS: please check the British National Formulary (BNF) and use the patient's electronic medical record to check for medicine interactions, by prescribing prednisolone (quantity = "0*" as per OSAC trial")**

Information about OSAC for patients:

This practice is taking part in some NHS-funded research looking into a new treatment for acute cough. Because of your cough you could really help us with this research.

It's a randomised trial, run by the University of Bristol. They want to see if a short course of oral steroids could help improve the worst symptoms and speed up recovery.

The steroid tablets are called prednisolone, which is widely prescribed for asthma and other inflammatory conditions, but it's not currently used in this country for cough. Taking part would involve you taking a five day course of prednisolone or placebo (we would not know which), measuring your peak flow expiratory rate, completing a daily symptom diary for up to 28 days or as long as you feel unwell, and receiving a weekly telephone call from the Trial Research Nurse for four weeks.

Would you like to know more about the research, and if so would you be willing for me or one of my clinical colleagues to do some checks as to whether you would be able to take part?

OSAC Trial Eligibility Criteria Laminated Card v1.3 (23 September 2013)

