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The Oral Steroids for Acute Cough (OSAC) Trial

Submission date 31/01/2013	**Recruitment status** No longer recruiting	[X] Prospectively registered [X] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 31/01/2013	**Overall study status** Completed	
Last Edited 17/02/2021	**Condition category** Respiratory	

Plain English summary of protocol

Background and study aims
Most people get at least one chest infection every year and a high proportion present to health services and need to take time off work/other responsibilities. Symptoms are frequently prolonged (lasting 3 to 4 weeks) and no treatment (including antibiotics) has been shown to reduce either symptom severity or duration. Despite this, and strong evidence that inappropriate antibiotic prescribing fuels the development of the antibiotic-resistant bacterial strains (including MRSA), around 75% of adults presenting to GPs are still prescribed antibiotics. Many of the symptoms of chest infections (cough, phlegm, shortness of breath and wheeze) overlap with those of asthma attacks. While there is good evidence that steroids help patients with asthma, very little research has been conducted to assess if steroids can have the same beneficial effects in non-asthmatic patients suffering from chest infections. More evidence is needed to help doctors to understand if a high dose of steroids (given by tablets) are better than antibiotics, and could help doctors and patients to rely less on antibiotics. A high dose has been selected to maximise the chances of the study detecting an effect. If effects are found, lower doses will be tested in the future.

Who can participate?
Non-asthmatic adults with a chest infection

What does the study involve?
Participants are randomly allocated to be given either a 5-day course of (active) steroid tablets or placebo (dummy) tablets. They are asked to complete a daily symptom diary for up to 4 weeks.

What are the possible benefits and risks of participating?
If the use of steroids was to reduce the annual cost of treating chest infections by as little as 1%, then the NHS would recoup the cost of the study in one year. Participation will not affect patients' access to all other aspects of usual care and, in an emergency, their doctor will be able to find out which treatment they were given.

Where is the study run from?
University of Bristol (UK)

When is the study starting and how long is it expected to run for?
February 2013 to April 2014

Who is funding the study?
National Institute for Health Research (NIHR) (UK)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
13751

Study information

Scientific Title
What is the clinical and cost effectiveness of oral steroids in the treatment of acute lower respiratory tract infection (LRTI)? A placebo controlled randomised trial

Acronym
OSAC

Study objectives
To test whether the use of oral prednisolone 40mg daily for 5 days will reduce the duration of moderately bad or worse cough, and its associated severity, by at least 20% when compared to no steroid treatment (usual care).

Ethics approval required
Old ethics approval format

Ethics approval(s)
12/SW/0180

Study design
Two-arm individually randomised placebo-controlled blinded superiority trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
GP practice

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Acute lower respiratory tract infection

Interventions
Oral prednisolone (40 mg daily) or matched placebo for up to five consecutive days

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Prednisolone

Primary outcome measure
Duration of moderately bad or worse cough (using a validated web/paper based symptom diary)

Secondary outcome measures
1. The mean of all symptom severity scores on days 2 to 4 (where day 1 is the day after the consultation day, measured using the symptom diary)
2. Antibiotic consumption (symptom diary)
3. Duration of steroid tablet use (symptom diary)
4. Total duration and severity of other symptoms (cough until very little problem; phlegm; wheeze; fever; chest pain; shortness of breath; sleep disturbance; activity disturbance; and feeling unwell) and abnormal peak flow (symptom diary)
5. Adverse events including reconsultation for a documented deterioration in illness or hospital

admission (symptom diary and primary care notes review)
6. Patient satisfaction with treatment and intention to consult for future similar illnesses (symptom diary)
7. Clinical diagnosis of asthma at 3 months (primary care notes review)
8. Quality of life using the EQ-5D (as recommended by NICE, web/paper based questionnaire)
9. NHS treatment and investigation (e.g. chest x-rays, reconsultation) costs (primary care notes review), out-of-pocket patient costs, and societal cost of time off work (symptom diary)

Overall study start date
01/02/2013

Completion date
30/04/2014

Eligibility

Key inclusion criteria
1. Aged 18 years or over
2. Consulting for an acute (<= 28 days) cough as the main presenting symptom
3. In the past 24 hours, the patient has had at least one of the screening symptoms listed below (a-d), localizing to the lower respiratory tract and suggestive of an acute lower respiratory tract infection (RTI):
3.1. Phlegm (sputum)
3.2. Chest pain
3.3. Shortness of breath
3.4. Wheeze
4. Patient and practice have sufficient time for consent and randomisation into the trial by the end of today
5. Patient able and willing to give informed consent themselves
6. Patient able and willing to complete the daily symptom diary themselves
7. Patient able and willing to receive weekly telephone calls from the trial team

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
UK Sample Size: 436

Key exclusion criteria
1. Known lung cancer or chronic lung disease (e.g. cystic fibrosis, COPD, bronchiectasis)
2. Has an 'active' diagnosis of asthma (for which any treatment has been given in the past 5 years)

3. The patient's RTI warrants same day hospital admission or immediate antibiotics (NB: use of delayed prescription does not preclude OSAC trial participation):

According to NICE guidelines, the patient warrants immediate antibiotic treatment by virtue of ONE OR MORE of the following:
1. Is clinically very unwell or has symptoms and signs suggestive of pneumonia, e.g. tachypnoea (>20bpm), unilateral chest signs or consolidation, or hypoxia (oxygen saturation <94%) or other systemic infection, e.g. suspected bacteraemia OR
2. Is 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

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:
1. Unplanned hospitalisation within the previous year
2. Type 1 or Type 2 diabetes
3. History of cardiac failure
4. Requires an antibiotic today to treat another infection unrelated to their acute cough, e.g. a co-existing cellulitis
5. Recently (<=1 month) used inhaled corticosteroids
6. Recently (<=1 month) used short (up to 2 weeks) course systemic corticosteroids
7. Currently using, or has previously (<=12 months) used systemic steroids for a cumulative period greater than 2 weeks, i.e. 'long-term' use
8. Known to be pregnant, is trying to conceive or is at risk of pregnancy (e.g. unwilling to take a reliable form of contraception) in the next month
9. Currently breast-feeding
10. This is not the patient's usual practice, i.e. patient is visiting or is not intending to stay with the practice for the 3 month trial follow up period
11. Previously randomised in the OSAC trial
12. Has been involved in another medicinal trial within the last 90 days or any other clinical research study within the last 30 days
13. 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
14. Known immune-deficiency, e.g. chemotherapy causing immunosuppression, asplenia or splenic dysfunction, advanced cancer or HIV infection
15. Has any of the following known contra-indications or cautions to oral steroids current OR previous history of:
15.1. Peptic ulcer disease
15.2. Osteoporosis
15.3. Previous TB
15.4. Glaucoma
15.5. No previous chickenpox AND known recent (<=28 days) history of close personal contact with chickenpox OR herpes zoster
15.6. Suspected ocular herpes simplex
15.7. Cushing's disease
15.8. Epilepsy
15.9. 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
15.10. Severe affective disorders, e.g. manic depression, previous steroid psychosis

15.11. Previous steroid myopathy
15.12. Intention to use a live vaccine in the next 3 months (NB: assess live vaccine status by cross-checking with BNF)
Current history only:
15.13. Uncontrolled diabetes (HbA1C > 8%)
15.14. Taking other interacting medication (e.g. phenytoin and anti-coagulants)
15.15. Uncontrolled hypertension
15.16. Any other BNF listed contra-indication or caution
15.17. Is unable to swallow tablets

Clinicians will be asked to use the British National Formulary (BNF) and their clinical prescribing systems to check for significant interactions for all patients. A SOP will be produced to describe the checking process.

Date of first enrolment
01/02/2013

Date of final enrolment
30/04/2014

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
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ROR
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Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research (NIHR) (UK) - School for Primary Care Research

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	07/03/2015		Yes	No
Results article	results	22/08/2017		Yes	No
Other publications	economic evaluation	18/02/2020	17/02/2021	Yes	No
HRA research summary			28/06/2023	No	No