Universität Basel

Research Project

Oral corticosteroids for post-infectious cough in adults: A double-blind randomised placebo-controlled trial in Swiss family practices (OSPIC)

Third-party funded project

Project title Oral corticosteroids for post-infectious cough in adults: A double-blind randomised placebo-controlled trial in Swiss family practices (OSPIC)
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Cough is one of the most common causes for seeking medical advice in general practices. Post-infectious cough is defined as lasting 3 to 8 weeks after an upper respiratory tract infection (URTI). It can be very bothersome, disabling in daily activities with substantial impact on physical and psychosocial health, leading to impaired quality of life (QoL). Recommendations for the management of post-infectious cough in primary care are scarce and incoherent. To provide a wide overview of treatment options for patients with post-infectious cough, we conducted and recently published a systematic review and meta-analysis of randomised clinical trials (RCTs) assessing the patient-relevant benefits and potential harms of available treatments. Only six eligible RCTs assessing different treatment regimens (i.e. inhaled fluticasone propionate, inhaled budesonide, salbutamol plus ipratropium-bromide, montelukast, nociception-opioid-1-receptor agonist, codeine, and gelatine) were identified. None of these RCTs found clear patient-relevant benefits and most had an unclear or high risk of bias.Post-infectious cough is thought to be mediated by inflammatory processes that are also present in exacerbations of asthma or chronic obstructive pulmonary diseases (COPD). There is strong evidence that oral corticosteroids for 5 days provide patient-relevant benefit without relevant harm for these conditions. Our systematic search identified no RCTs evaluating oral corticosteroids for post-infectious cough. Thus, a high quality RCT assessing the benefits and harms of orally administered corticosteroids for post-infectious cough is needed.Aim: To assess whether a 5-day treatment with oral corticosteroids provides patient-relevant benefits by improving the cough-related QoL and reducing the duration and intensity of post-infectious cough in adult primary care patients.Methods: The proposed study is a multicentre, 1:1 randomised, parallel-group, placebo-controlled, superiority trial with blinded patients, general practitioners (GP), and outcome assessors in a primary health care setting. We plan to include 204 patients aged 18 or older seeing their GP for a cough lasting 3 to 8 weeks following an URTI. Any concurrent disease possibly explaining the symptoms, such as pneumonia, asthma, COPD, gastroesophageal reflux disease, allergic rhinitis, or cancer will be ruled out before trial inclusion. Patients will receive oral corticosteroid treatment (equivalent of 40 mg prednisone once daily) for 5 days or placebo for 5 days.The primary outcome is cough-related QoL assessed by the Leicester Cough Questionnaire (LCQ) score 14 days after randomisation. Secondary outcomes are i) cough-related QoL (at day 7, 28, and 3 months), ii) cough-related QoL sub-domains physical, psychological, and social, iii) overall cessation of cough, iv) re-consultations at GP and/or hospitalisations, v) total adverse events (AE), and vi) serious adverse events (SAE). All

outcomes will be assessed through follow-up phone calls by study nurses 7, 14, 28 days, and 3 months after randomisation. Clinical follow-up visits with the GP are at the discretion of the patient and the GP.Assumptions for sample size estimation are informed by our systematic review. 204 patients are required to detect a statistically significant minimal clinically important difference of 1.3 of the LCQ score at 14 days (primary outcome; power 80%, two-sided significance level 5%, drop-out-rate 10%). Primary analysis will be done with ANCOVA (analysis of covariance) according to the intention to treat principle. Baseline LCQ scores, duration of cough, age, sex, and smoking status will be covariates.Importance: This will be the first RCT investigating whether oral corticosteroids are beneficial and safe in patients with post-infectious cough, which would have a substantial impact on the well-being and management of these patients in Switzerland and beyond.

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