





Feasibility study of Pelargonium sidoides root extract, EPs®7630 (Kaloba®), for the treatment of acute cough due to lower respiratory tract infection (LRTI) in adults: a double blind, placebo controlled randomised trial

Catherine Simpson¹, Merlin Willcox², Gareth Griffiths¹, Paul Little², Alastair Hay³, Chris Butler⁴, Lily Yao⁵, Fran Webley¹, Amy Whitehead¹, Jennifer Bostock⁶, Margaret Bell⁶, Michael Moore³ (Chief Investigator).

1. Southampton Clinical Trials Unit; 2. Primary Care and Population Sciences, University of Southampton; 3. Population Health Sciences, University of Bristol; 4. Nuffield Department of Primary Care Health Sciences, University of Oxford; 5. University of Leicester; 6. PPI representative

Background and Rationale

Background

 \bullet

lacksquare

Adults aged 18+ years	160
Main symptom:	100

- Antibiotic resistance is rising and is linked to prescribing in primary care
- Acute LRTI is one of the most common respiratory conditions treated by GPs and the majority (60%) of patients will be prescribed antibiotics, despite lack of evidence of benefit
- The symptoms of non-pneumonic LRTIs usually settle without complication but the cough can last for around an average of 21 days
- Antibiotics have little effect on the duration of symptoms but if an effective method of symptom control could be identified then antibiotic uptake could be reduced
- **Pelargonium sidoides root extract EPs®7630 (Kaloba®)** is a traditional herbal medicinal product used to relieve the symptoms of upper respiratory tract infections including cough
- A Cochrane review suggests that *Pelargonium sidoides* root extract has some benefit in LRTI



Aim

 To determine the feasibility of running a full-scale double blind randomised controlled trial (RCT) of Pelargonium sidoides root extract in the UK primary care setting

Consequences

If HATRIC leads to a successful full RCT that shows
Pelargonium sidoides root extract is an effective treatment
for the symptoms of LRTI, prescription of antibiotics for LRTIs

may decline



Recruitment and Retention Strategies

- Complete symptom diary (up to 28 days after presentation; stop 2 days after complete resolution of symptoms)
- GP notes review 28 days after randomisation

Results

9 month recruitment period (Mar - Dec 2018)

- 134 patients recruited
- 52 to the tablet arms & 82 to the liquid arms
- 107 (80%) diaries obtained with all key information
- 4 patients lost to follow up





Contact: catherine.simpson@soton.ac.uk

This study is funded by the NIHR School of Primary Care Research (project reference 336). The views expressed are those of the authors and not necessarily those of the MHS, the NIHR or the Department of Health and Social Care.

