

HATRIC - Herbal Alternative Treatment (Pelargonium) for lower Respiratory tract Infections with Cough in adults

Submission date 02/07/2018	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 16/08/2018	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 01/02/2021	Condition category Infections and Infestations	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

Acute lower respiratory infection is common and despite the lack of evidence of benefit antibiotics are often prescribed. Identifying a safe and effective method of symptom control would likely further reduce antibiotic uptake. Pelargonium, a herbal product extracted from the root of *P. sidoides* in either liquid or tablet form, has been found to have some benefit in treating cough symptoms. The aim of this study is to determine the feasibility of conducting a full trial of Pelargonium sidoides root extract as an alternative to antibiotics for lower respiratory tract infections in UK primary care.

Who can participate?

Patients aged 18 and over with an acute cough (less than 21 days' duration) associated with a lower respiratory infection, where pneumonia is not suspected

What does the study involve?

Participating GP practices are randomly allocated to give either the liquid or tablet preparation, and within each practice, patients are randomly allocated to take either Pelargonium sidoides root extract EPs @7630 or a placebo (dummy medicine). The use of a delayed prescription for antibiotics is encouraged, but GPs are also able to offer either an immediate prescription for antibiotics or no prescription. Patients are asked to take the medication three times a day, 30 minutes before meals, until 2-3 days after symptom resolution. Patients are asked to complete a daily symptom diary for up to 28 days. Patients can stop completing the diary 2 days after complete resolution of symptoms. A notes review is undertaken after 28 days to document return visits to the GP with a lower respiratory tract infection.

What are the possible benefits and risks of participating?

It is not known whether participants will have any additional benefit from taking part in this trial. However their participation will help to give important information about how best to treat people with chest infections in the future. It is unlikely but participants may experience mild side effects from taking the trial medication.

Where is the study run from?

1. Abbeywell surgery
2. Chawton Park Surgery
3. Oaks Healthcare – Cowplain Family Practice Site
4. Friarsgate Practice
5. Highcliffe Medical Centre
6. Homewell.Curlew Practice
7. Liphook and Liss Surgery
8. Lordshill Health Centre
9. Mulberry House Surgery
10. Park & St Francis Surgery
11. Salisbury Medical Practice
12. Solent NHS Trust
13. Swan Medical Group
14. Swanage Medical Practice
15. The Adam Practice
16. The Andover Health Centre
17. The Cambridge Practice
18. Three Chequers Medical Practice
19. Vine Medical Group
20. Wareham Surgery

When is the study starting and how long is it expected to run for?

April 2017 to March 2019

Who is funding the study?

National Institute for Health Research (NIHR) (UK)

Who is the main contact?

Mrs Catherine Simpson

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Contact information

Type(s)

Scientific

Contact name

Mrs Catherine Simpson

Contact details

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Additional identifiers

Clinical Trials Information System (CTIS)

2016-004598-42

Protocol serial number

35629

Study information

Scientific Title

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

Acronym

HATRIC

Study objectives

Acute lower respiratory infection is common and despite the lack of evidence of benefit antibiotics are often prescribed. Identifying a safe and effective method of symptom control would likely further reduce antibiotic uptake. A Cochrane review suggests pelargonium, a herbal product extracted from the root of P. Sidoides in either liquid or tablet formulation, has some benefit in treating cough symptoms. The objective of this trial is to determine the feasibility of conducting a fully powered trial of Pelargonium sidoides root extract as an alternative to antibiotics for lower respiratory tract infections in UK primary care.

Ethics approval required

Old ethics approval format

Ethics approval(s)

South Central – Berkshire B, 05/01/2018, ref: 17/SC/0653

Study design

Randomised; Interventional; Design type: Treatment, Drug

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Specialty: Primary Care, Primary sub-specialty: Infectious diseases and microbiology; UKCRC code/ Disease: Infection/ Other viral diseases

Interventions

This is a multicentre, double-blind placebo-controlled feasibility trial of Pelargonium sidoides root extract EPs®7630 (Kaloba®).

The trialists aim to recruit 160 adults, 18 years and over, presenting to their GP with an acute cough (≤ 21 days' duration) as their main symptom and with symptoms localising to the lower respiratory tract (e.g. sputum, chest pain, dyspnoea, wheeze), for which an infective diagnosis is judged very likely.

Sites will be randomised to one of two groups (tablet or liquid preparation) and within each site, patients will be randomised to active or placebo IMP.

Group 1: Liquid Pelargonium sidoides root extract EPs®7630

Group 2: Liquid placebo

Group 3: Tablets of Pelargonium sidoides root extract EPs®7630

Group 4: Placebo tablets

The use of the delayed prescription strategy for antibiotics will be encouraged but clinicians will be able to offer one of three following antibiotic strategies in addition to the randomised intervention:

1. Immediate antibiotics
2. Delayed antibiotics
3. No antibiotics

Participants will be provided with a course of trial medication and a prescription for antibiotics, if considered necessary by the recruiting clinician. If the recruiting clinician uses the delayed prescription strategy then patients will be asked to delay starting taking the antibiotic for 7-10 days.

Patients will be asked to take the trial medication 3 times a day, 30 minutes before meals, until 2-3 days after symptom resolution. Participants will be asked to complete daily diary data for up to 28 days after presentation. They can stop completing the diary 2 days after complete resolution of symptoms.

Patients will receive follow up phone calls from the research team at the Southampton Clinical Trials Unit (SCTU) at intervals following randomisation to prompt diary completion and return. Participants will be given a £5 shopping voucher on recruitment and when they have returned a fully completed diary.

A notes review will be undertaken 28 days after randomisation to document return visits to the GP with a LRTI.

Intervention Type

Other

Phase

Phase II

Primary outcome(s)

The objective is to determine the feasibility of conducting a fully powered trial of Pelargonium sidoides root extract as an alternative to antibiotics for lower respiratory tract infections in UK primary care. Feasibility objectives and endpoints used to evaluate are detailed below:

1. Eligibility: Number of patients included in and number excluded, with reasons, from the trial from on-site screening logs
2. Recruitment: Ability to recruit patients into the intervention from those attending primary care settings from on-site enrolment records – monthly rate/site adjusted for site list size

3. Randomisation: Willingness to be randomised from the proportion of eligible patients recruited
4. Retention: Across the duration of the intervention and return of a fully completed diary from quantitative data from enrolment, withdrawal rate from study and completion of outcome measures
5. Intervention compliance from diary data and returned medication
6. Patient preference for liquid/tablet formulation from diary data, returned medication and recruitment data
7. Acceptability of the patient diaries, patients' willingness to complete them and the importance of telephone/text contact from quantitative data collection - percentage of patients returning completed diaries
8. Success of delayed antibiotic strategy from diary data on day antibiotics commenced
9. Need for stratification by antibiotic strategy in main study from proportion allocated to immediate and delayed antibiotic strategy
10. To inform sample size for future trials from rate of outcome measures in the control group.
11. To identify the key resource items to be collected and how often to collect EQ-5D-5L questionnaires in the main trial from data collected in patient diaries and case note reviews

Key secondary outcome(s)

There are no secondary outcome measures

Completion date

30/07/2019

Eligibility

Key inclusion criteria

1. Adults 18 years and over
2. Presenting with an acute cough (≤ 21 days' duration) as their main symptom
3. Presenting with symptoms localising to the lower tract (e.g. sputum, chest pain, dyspnoea, wheeze), for which an infective diagnosis is judged very likely
4. Willing and able to give written informed consent

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

Total final enrolment

134

Key exclusion criteria

1. Suspected pneumonia (i.e., complicated lower-respiratory-tract infection) on the basis of focal chest signs (focal crepitations, bronchial breathing) and systemic features (severe breathlessness, high fever, vomiting, severe diarrhoea)
2. Signs of severity which may warrant hospital admission (e.g. SpO₂ < 91%, Systolic BP < 90mmHg, Heart rate > 130)
3. Exacerbation of COPD
4. Serious chronic disorders where immediate antibiotics are needed (e.g. cystic fibrosis, valvular heart disease)
5. Unable to give informed consent or complete trial paperwork (including the patient diary)
6. Difficulty reading and understanding English and therefore unable to give informed consent or complete the trial paperwork (including the patient diary)
7. Known or suspected pregnancy
8. Women at risk of pregnancy (i.e. not on effective contraception – combined oral contraceptive pill, an intrauterine hormonal device or subcutaneous hormonal implant)
9. Currently breastfeeding
10. Known immunodeficiency state or chemotherapy
11. Currently taking oral steroids
12. Using a Pelargonium sidoides / Kaloba® preparation and unwilling or unable to discontinue for the study period.
13. Hypersensitivity to pelargonium sidoides preparations or to the Kaloba brand
14. Increased tendency to bleeding or is taking coagulation-inhibiting drugs (e.g. warfarin)
15. Severe hepatic and renal diseases (Chronic Kidney Disease Stage 4, GFR < 30), as no adequate data are available in these areas
16. Rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption (tablet formulation only)
17. Previously entered the HATRIC trial
18. Recruited to another interventional trial in the previous 6 weeks

Date of first enrolment

14/03/2018

Date of final enrolment

21/12/2018

Locations

Countries of recruitment

United Kingdom

England

Study participating centre

Abbeywell surgery

Nightingale site

Great well drive

Romsey

United Kingdom

SO51 7QN

Study participating centre

Chawton Park Surgery

Chawton Park Road
Alton
United Kingdom
GU34 1RJ

Study participating centre

Oaks Healthcare – Cowplain Family Practice Site

26-30 London Road
Cowplain
United Kingdom
PO8 8LD

Study participating centre

Friarsgate Practice

Stockbridge Road
Winchester
United Kingdom
SO22 6EL

Study participating centre

Highcliffe Medical Centre

248 Lymington Road
Highcliffe
Christchurch
United Kingdom
BH23 5ET

Study participating centre

Homewell.Curlew Practice

Havant Health Centre
Civic Centre Road
Havant
United Kingdom
PO9 2AQ

Study participating centre

Liphook and Liss Surgery

Station Road
Liphook
United Kingdom
GU30 7DR

Study participating centre

Lordshill Health Centre

Lordshill District Centre
Southampton
United Kingdom
SO16 8HY

Study participating centre

Mulberry House Surgery

7 St Denys Road
Southampton
United Kingdom
SO17 2GN

Study participating centre

Park & St Francis Surgery

Pilgrims Close
Chandlers Ford
United Kingdom
SO53 4ST

Study participating centre

Salisbury Medical Practice

Fisherton House
Fountain Way
Wilton Road
Salisbury
United Kingdom
SP2 7FD

Study participating centre

Solent NHS Trust

Clinical Research Office
Room FW. B. 3178. A
Royal South Hants Hospital

Britons Terrace
Southampton
United Kingdom
SO14 0YG

Study participating centre
Swan Medical Group
Swan Street
Petersfield
United Kingdom
GU32 3AB

Study participating centre
Swanage Medical Practice
Station Approach
Swanage
United Kingdom
BH19 1HB

Study participating centre
The Adam Practice
Upton Health Centre
Blandford Road North
Upton
Poole
United Kingdom
BH16 5PW

Study participating centre
The Andover Health Centre
Charlton Road
Andover
United Kingdom
SP10 3LD

Study participating centre
The Cambridge Practice
276 Lower Farnham Road
Aldershot
United Kingdom
GU11 3RB

Study participating centre
Three Chequers Medical Practice
Three Swans Surgery
Rollestone St
Salisbury
United Kingdom
SP1 1DX

Study participating centre
Vine Medical Group
Waterlooville Health Centre
Dryden close
Waterlooville
United Kingdom
PO7 6AJ

Study participating centre
Wareham Surgery
Streche Road
Wareham
United Kingdom
BH20 4PG

Sponsor information

Organisation
University of Southampton

ROR
<https://ror.org/01ryk1543>

Funder(s)

Funder type
Government

Funder Name

Results and Publications

Individual participant data (IPD) sharing plan

The data sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary

Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	29/01/2021	01/02/2021	Yes	No
Protocol article	protocol	31/07/2019	07/08/2019	Yes	No
HRA research summary			28/06/2023	No	No