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Safety and intake effect of EPs® 7630 (an extract of the roots of Pelargonium sidoides)

Submission date
12/09/2014

Recruitment status
No longer recruiting

Registration date
29/12/2014

Overall study status
Completed

Last Edited
25/04/2019

Condition category
Infections and Infestations

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
The common cold is a mild upper respiratory illness that affects people of all ages. Symptoms include headache, sneezing, sore throat, nasal discharge (runny nose), nasal obstruction (blocked nose), cough and feeling tired. Palargonium sidoides (EPs® 7630) is an extract of a South African medicinal plant. There is evidence to suggest that it has antiviral effects and boosts the body's ability to fight the common cold. We want to see whether taking EPs® 7630 over a 4 month period is safe and whether it can protect against, and act against, common cold infections.

Who can participate?
Adults aged at least 18 years who have experienced at least two colds in the last 12 months.

What does the trial involve?
Participants are randomly allocated into one of two groups. Those in group 1 are given EPs® 7630 tablets for 4 months. Those in group 2 are given a placebo (dummy) tablet for 4 months. Participants in both groups take one tablet three times a day (in the morning, midday and evening) when they are not suffering from a cold. When participants in either group think they are getting a cold, they document this in a diary and take two tablets three times a day (in the morning, midday and evening) for 14 consecutive days. Each participant receives follow-up visits after 1, 2 and 3 months in order to record their state of health. After the fourth month, they come back to the study center for the final visit.

What are the possible benefits and risks of participating?
Participants may benefit from a reduction in their common cold symptoms and an improvement in their general well-being. They may also benefit from the diagnostic measures (e.g. general physical examination, laboratory test, etc.) applied at their first and last scheduled visits. During blood sampling, a small risk of infection may occur, but this can be reduced by the use of adequate techniques. It is expected that the participants will benefit from the treatment with EPs® 7630 when they suffer from symptoms of common cold during the study. As EPs® 7630 is well tolerated according to the data gathered so far, there is no major risk to taking EPs® 7630. Gastrointestinal complaints may occur during treatment with EPs® 7630, but this is not common. In rare cases, mild bleeding from the gums or nose may also occur. Hypersensitivity reactions are known to occur but are rare. There have been some reports of liver problems but a

link between this and the taking of EPs® 7630 has not been proven. The further examinations are not associated with any special risk for the participants.

Where is the trial run from?
Common Cold Centre at the Cardiff University in Wales (UK)

When is the study starting and how long is it expected to run for?
March 2014 to March 2015.

Who is funding the trial?
Dr. Willmar Schwabe GmbH & Co. KG (Germany)

Who is the main contact?
F. A. Malek, M.D., Ph.D.
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number
2013-004977-28

IRAS number

ClinicalTrials.gov number
NCT02174653

Secondary identifying numbers
701079.01.013

Study information

Scientific Title
Safety and intake effect of EPs® 7630 (an extract of the roots of Pelargonium sidoides): a randomised controlled trial

Acronym
N/A

Study objectives
The main objective of this clinical trial is to evaluate the safety of EPs® 7630 intake - used as continuous protection and at the onset of cold symptoms - in adult participants during a long-term (4 months) medication. Due to the sparseness of empirical data in the population and this setting, no confirmatory hypotheses are formulated and the data will be analysed descriptively.

Ethics approval required
Old ethics approval format

Ethics approval(s)
South East Wales Research Ethics Committee, Cardiff; 29/01/2014; ref. 14/WA/0015

Study design
Prospective monocentric randomised double-blind placebo-controlled parallel groups

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Home

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Common cold

Interventions
The trial duration per participant is four months. The participants are randomly divided into three treatment groups:

Group 1:
During the common cold free period: One film-coated tablet (20 mg) three times a day
During a common cold episode: Two film-coated tablets (1 x 20 mg and 1x placebo) three times a day (in the morning, midday and evening; total daily dose 60 mg) over the individual treatment duration of 14 consecutive days.

Group 2:
During the common cold free period: One film-coated tablet (20 mg) three times a day

During a common cold episode: Two film-coated tablets (2 x 20 mg = 40 mg) three times a day (in the morning, midday and evening; total daily dose 120 mg) over the individual treatment duration of 14 consecutive days.

Group 3:
During the common cold free period: One film-coated tablet (placebo) three times a day
During a common cold episode: Two film-coated tablet (placebo) three times a day (in the morning, midday and evening) over the individual treatment duration of 14 consecutive days.

All participants undergo following scheduled visits:
Visit 1: Day 0 (baseline)
Visit 2: 1 month ± 2 days after randomisation
Visit 3: 2 months ± 2 days after randomisation
Visit 4: 3 months ± 2 days after randomisation
Visit 5: 4 months ± 2 days after randomisation (final visit)

Intervention Type
Supplement

Primary outcome measure
Occurrence of Adverse Drug Reactions (ADRs) during the 4 months treatment.

Secondary outcome measures
1. Occurrence of Adverse Events (AEs) during the 4 months treatment
2. Protective effects
3. Effects during a cold episode
Daily documentation of AEs, common cold episodes and medication intake in participant's diary

Overall study start date
27/03/2014

Completion date
31/08/2016

Eligibility

Key inclusion criteria
1. Adult male or female participant (at least 18 years old)
2. Participant provided a written informed consent in accordance with the legal requirements
3. Participant with willingness and ability to comply with all procedures of the clinical trial and be available for the duration of the study
4. Participant is of good physical and mental condition
5. Participant experienced at least 2 colds per year in the last 12 months

Participant type(s)
Patient

Age group
Adult

Lower age limit

18 Years

Sex
Both

Target number of participants
720

Total final enrolment
798

Key exclusion criteria
1. Chronic respiratory tract or lung disease (e.g. chronic bronchitis, COPD, bronchial asthma, cystic fibrosis, active pulmonary tuberculosis, lung cancer)
2. History of heart, renal, liver, neuromuscular disease and/or immunosuppression
3. Known allergic bronchial asthma
4. Known or suspected congenital anomalies of heart, kidney, liver, or mental disabilities
5. Participant with concomitant medications that might impair the interpretation of trial results (e.g. herbal medications for common cold other than the investigational product, or pain relief medications other than Paracetamol or Ibuprofen)
6. Women of child-bearing potential with no adequate and effective contraception (MHRA, 2010):
6.1. Established use of oral, injected or implanted hormonal methods of contraception
6.2. Placement of an intrauterine device (IUD) or intrauterine system (IUS)
6.3. Barrier methods of contraception: Condom and/or Occlusive cap (diaphragm or cervical /vault caps) with spermicidal foam/gel/film/cream/suppository
6.4. Sexual abstinence
6.5. Vasectomised partner
7. Female participant who is pregnant, lactating or planning pregnancy during the course of the clinical trial
8. Participant with cold symptoms at inclusion
9. Current intake of antimicrobial and/or antiviral medication for any reason
10. Participant with known or suspected history of alcohol or drug abuse
11. Heavy smoking (more than 10 cigarettes per day)
12. Psychiatric disorders which may influence the results of the trial, epilepsy, or suicide attempts
13. Planned surgical intervention during the trial
(14) Known gastrointestinal disorders with uncertain absorption of orally administered medication (e.g. partial or total gastrectomy, enterectomy, inflammatory bowel disease, celiac disease, symptomatic lactose intolerance, disbacteriosis) or associated with diarrhoea
15. Known or suspected hypersensitivity to the active substance or to any of the excipients of the investigational product
16. Known clinically relevant laboratory abnormalities
17. Participant with increased tendency to bleed, especially nasal or gingival bleeding
18. Previous (within the last 3 months prior to visit 1) or concomitant treatment with coagulation-inhibiting drugs such as warfarin
19. Participation in a further clinical trial at the same time or within the last 4 weeks prior to inclusion into the present study
20. Previous randomisation in the present clinical study
21. Irresponsible subjects or those unable to understand nature, meaning and consequences of the trial

Date of first enrolment
27/03/2014

Date of final enrolment
31/03/2015

Locations

Countries of recruitment
United Kingdom

Wales

Study participating centre
Common Cold Centre
Sir Martin Evans Building
Museum Avenue
Cardiff
United Kingdom
CF10 3AX

Sponsor information

Organisation
Dr. Willmar Schwabe GmbH & Co. KG (Germany)

Sponsor details
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76227

Sponsor type
Industry

Website
http://www.schwabepharma.com

ROR
https://ror.org/043rrkc78

Funder(s)

Funder type
Industry

Funder Name
Dr. Willmar Schwabe GmbH & Co. KG (Germany)

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 expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Basic results				No	No
HRA research summary			28/06/2023	No	No