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# Evaluation of safety and tolerability of Pelargonium sidoides extract EPs® 7630 in children (1 to 5 years old) suffering from acute bronchitis

**Submission date**
14/06/2012

**Recruitment status**
No longer recruiting

**Registration date**
03/07/2012

**Overall study status**
Completed

**Last Edited**
23/05/2014

**Condition category**
Respiratory

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

## Plain English summary of protocol

Background and study aims
Acute respiratory illnesses are a common reason for seeking medical care. Apart from rhinitis, acute bronchitis is the most commonly diagnosed disease in pediatric practices. Acute bronchitis is characterized by the sudden onset of cough and production of sputum (a mixture of saliva and mucus) in a patient with no history of chronic pulmonary (lung) disease and no evidence of pneumonia or sinusitis. It is caused by a viral infection in the majority of cases. In Germany, EPs® 7630 solution and EPs® 7630 syrup are approved by the German Regulatory Authority for the indication acute bronchitis for the use by patients from the age of 1 year. The aim of this study is to evaluate the safety and tolerability of treatment with EPs® 7630 syrup in comparison to EPs® 7630 solution in patients between 1 and 5 years old suffering from acute bronchitis symptoms. During the study course the patients´ health status will also be assessed.

Who can participate?
Children aged between 1 and 5 years suffering from symptoms related to acute bronchitis that have started within 72 hours before inclusion into the study.

What does the study involve?
If you have agreed for your child to take part your childs doctor will first diagnose whether your child is eligible for the study. Your childs doctor will conduct a general physical examination, and measure height, weight and body temperature. He will carry out heart and respiratory rate measurements. The examination includes assessment of the severity of respiratory tract infection symptoms and general symptoms related to acute bronchitis. He also will collect a blood sample. If your child meets all criteria for inclusion your child will be randomly allocated to receive either EPs® 7630 solution or EPs® 7630 syrup. Your childs doctor will tell you to which treatment group your child belongs. Throughout the 7-day treatment period, your child has to take the study medication orally three times a day. Seven days after the start of treatment you will attend a second visit and the examinations of the first visit will be repeated. You will also be asked about the change of your childs health status and how satisfied you are with the

treatment. As it is a safety study your childs doctor also will ask you about any undesired effects your child was suffering from during the week on study medication.

What are the possible benefits and risks of participating?
EPs® 7630 may improve your childs bronchitis symptoms. By participating in the study your child will help us to gain more data on the safety and tolerability of EPs® 7630 in children with acute bronchitis. Based on the very good tolerability and safety profile of EPs® 7630 solution and EPs® 7630 syrup in this age group as shown in previous studies, there is no major risk linked to the intake of EPs® 7630. Uncommon side-effects include stomach pain, heartburn, nausea or diarrhoea, and in rare cases there may be mild bleeding from the gums or nose, skin rash, nettle rash, or itching of the skin and mucous membranes. In very rare cases serious hypersensitivity reactions with swelling of the face, breathlessness and drop in blood pressure may occur. Pain and bruising may occur during blood sampling and there is a small risk of infection, but this can be reduced by the use of adequate techniques. The further examinations are not associated with any risk for your child.

Where is the study run from?
The study takes place in 40 centres (paediatric practices, general practices) in Germany.

When is the study starting and how long is it expected to run for?
The study ran from October 2011 until March 2013.

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

Who is the main contact?
F. A. Malek, M.D., Ph. D.
fathi_abdul.malek@schwabe.de

# Contact information

### Type(s)
Scientific

### Contact name
Dr Fathi Abdul Malek

### Contact details
Dr. Willmar Schwabe GmbH & Co KG
Clinical Research Department
Willmar-Schwabe-Str. 4
Karlsruhe
Germany
76227

# Additional identifiers

### EudraCT/CTIS number

### IRAS number

### ClinicalTrials.gov number

### Secondary identifying numbers
701003.01.010

# Study information

### Scientific Title
Safety and tolerability of Pelargonium sidoides extract EPs® 7630 in children (1 to 5 years old) suffering from acute bronchitis: a randomised controlled trial

### Study objectives
The primary aim of the study is to obtain information about the safety of a 7-day treatment with the EPs® 7630 syrup in comparison to the EPs® 7630 solution in children between 1 and 5 years of age suffering from acute respiratory tract infection symptoms related to acute bronchitis. Since this study is a randomised open-label safety-study no hypotheses are formulated and the data will be analysed descriptively.

### Ethics approval required
Old ethics approval format

### Ethics approval(s)
Ethics Committee, Medical Association of Westfalen-Lippe and the Medical Faculty of Wilhelms-University of Westfalen, [Ethik-Kommission der Ärztekammer Westfalen-Lippe und der Medizinischen Fakultät der Westfälischen Wilhelms-Universität], 25/10/2011, ref: 2011-389-f-A

### Study design
Prospective multi-centre randomised open-label safety study

### Primary study design
Interventional

### Secondary study design
Randomised controlled trial

### Study setting(s)
Hospital

### 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
Acute bronchitis

### Interventions

2.5 ml EPs® 7630 syrup 3 times/day or 10 drops EPs® 7630 solution 3 times/day for 7 consecutive days

### Intervention Type
Other

### Phase
Not Applicable

### Primary outcome measure
Safety:
1. Frequency, severity, and nature of adverse events measured throughout the treatment period (7 days of treatment).
2. Changes in vital signs measured at day 7
3. Changes in laboratory values measured at day 7

### Secondary outcome measures
Patient´s health status:
1. Changes in individual respiratory tract infection symptoms related to acute bronchitis as well as the total symptoms score
2. Treatment outcome using the Integrative Medicine Outcomes Score (IMOS) as assessed by the investigator as well as by the legal representatives of the patients
3. Satisfaction with the treatment using the Integrative Medicine Patient Satisfaction Scale (IMPSS) as assessed by the legal representatives of the patients

Measured at day 7

### Overall study start date
01/10/2011

### Completion date
30/06/2013

## Eligibility

### Key inclusion criteria
1. Patient from 1 year to 5 years old
2. Patient is suffering from symptoms related to acute bronchitis (the patients must have at least two of the three bronchitis-relevant symptoms, i.e. coughing, pulmonary rales at auscultation, and dyspnoea)
3. Patient for whom the legal representatives have given a written informed consent in accordance with the legal requirements
4. Start of symptoms <= 72 hours prior to inclusion into the study

### Participant type(s)
Patient

### Age group
Child

### Lower age limit
1 Years

### Upper age limit
5 Years

### Sex
Both

### Target number of participants
600

### Key exclusion criteria
1. Patient with indication of treatment with antibiotics (e.g. suspected pneumonia)
2. Patient with diagnosed or suspected pneumonia, rhinosinusitis, otitis media, or group A beta-hemolytic streptococcal (GABHS) tonsillo-pharyngitis
3. Patient with suspicion of foreign body aspiration
4. Known or suspected allergic rhinitis or other allergic diseases
5. History of asthma bronchiale or recurrent bronchitis
6. History of heart, renal, or liver diseases and/or immunosuppression
7. Known or suspected congenital anomalies of heart, kidney, liver, or mental disabilities
8. Known or suspected hypersensitivity against EPs® 7630 or other excipients of the investigational products
9. Known or suspected gastro-esophageal reflux disease (GERD)
10. Patient with tendency to bleed, especially nose or gingival bleeding
11. Previous (within the last 6 weeks prior to inclusion into the clinical trial) or concomitant treatment with anti-coagulants
12. Known or suspected gastrointestinal disorders (e.g. inflammatory bowel disease, celiac disease, symptomatic lactose intolerance, disbacteriosis, other disorders associated with diarrhoea)
13. Participation in a further clinical trial at the same time or within the last 4 weeks prior to inclusion into the present study
14. Previous participation in the present clinical study

### Date of first enrolment
01/10/2011

### Date of final enrolment
30/06/2013

## Locations

### Countries of recruitment
Germany

### Study participating centre

**Dr. Willmar Schwabe GmbH & Co KG**
Karlsruhe
Germany
76227

# Sponsor information

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

**Sponsor details**
c/o Dr Fathi Abdul Malek
Clinical Research Department
Willmar-Schwabe-Straße 4
Karlsruhe
Germany
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 provided at time of registration