PLEASE NOTE: *This study has been imported from ClinicalTrials.gov without additional data checks.*

Trial Description

Title

Tolerance and Effect of a Prophylactical Treatment With a Cough Medicine Containing Ivy Leaves Dry Extract in Children With Recurrent Wheezy Bronchitis

Trial Acronym

[---]*

URL of the trial

[---]*

Brief Summary in Lay Language

To evaluate the effect of a prophylactical therapy with a cough medicine containing ivy leaves dry extract on the frequency of recurrent wheezy bronchitis in toddlers, on the duration of the bronchitis episodes, on the severity and the additional drug demand. A prolonged asymptomatic episode between each wheezy bronchitis due to the therapy is assumed.

Brief Summary in Scientific Language

[---]*

Organizational Data

- DRKS-ID: **DRKS00005899**
- Date of Registration in DRKS: **2015/03/03**
- Date of Registration in Partner Registry or other Primary Registry: **2014/01/13**
- Investigator Sponsored/Initiated Trial (IST/IIT): **yes**
- Ethics Approval/Approval of the Ethics Committee: **[---]***
- (leading) Ethics Committee Nr.: **[---]***

Secondary IDs

- Primary Registry-ID: **NCT02045550 (ClinicalTrials.gov)**
- Sponsor-ID: **HeHe02 (Technische Universität Dresden)**

Health condition or Problem studied

- Free text: **Acute Wheezy Bronchitis**
- Free text: **Recurrent Bronchitis**
- ICD10: **J20 - Acute bronchitis**

Interventions/Observational Groups

- Arm 1: **Drug: Prospan Syrup**

Characteristics

- Study Type: **Interventional**
- Study Type Non-Interventional: **[---]***
- Allocation: **Randomized controlled trial**
- Blinding: **[---]***
- Who is blinded: **patient/subject, investigator/therapist**
- Control: **Placebo**
- Purpose: **Prevention**
- Assignment: **Parallel**
- Phase: **II**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **[---]***

Primary Outcome

- the time to event (next bronchitis episode) rate during and after treatment period; time frame: three months

Secondary Outcome

- days and percentage of days without bronchitis during and after treatment period; time frame: 3 months
- days and percentage of days without bronchitis during treatment period; time frame: three months

Countries of recruitment

- DE **Germany**

Locations of Recruitment

- **Universitätsklinikum Carl Gustav Carus, Klinik und Poliklinik für Kinder- und Jugendmedizin, Dresden**

Recruitment

- Planned/Actual: **[---]***
- (Anticipated or Actual) Date of First Enrollment: **2014/01/31**
- Target Sample Size: **60**
- Monocenter/Multicenter trial: **[---]***
- National/International: **[---]***

Inclusion Criteria

- Gender: **Both, male and female**
- Minimum Age: **1 Years**
- Maximum Age: **3 Years**

Additional Inclusion Criteria

1. Medical diagnosis of ≥3 episodes of wheezy bronchitis within the pre-vious 12 months

2. Children aged from 1 to 3 years (girls and boys)

3. Signed Informed Consent of the legal guardians to participate in the trial after written and verbal briefing by the Investigator

4. No allergic sensitization

5. Allowance to contact the familys pediatrician for medical history of wheezy bronchitis episodes

Exclusion criteria

1. Anamnestically known intolerance/allergy to one of the drugs applied or to their ingredients or to drugs of similar chemical structure

2. Participation of the patient in another clinical trial within the last four weeks before enrollment in this trial

3. Evidence suggesting that the patient or their legal representative is not likely to follow the trial protocol (e.g. lacking compliance)

4. Inability to document the symptoms in a symptom log book or questionnaire; inability to take the trial medication properly

5. Any regular therapy except Vitamin D or Fluoride

6. Chronic illnesses of different aetiology

7. Premature birth or diagnosis of bronchopulmonary dysplasia

8. Gastro-oesophageal reflux

9. Hereditary fructose intolerance

Addresses

- **Primary Sponsor**

  Technische Universität Dresden

  Telephone: **[---]***
  Fax: **[---]***
  E-mail: **[---]***
  URL: **[---]***

- **Contact for Scientific Queries**

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Sources of Monetary or Material Support

- **[---]***

Bitte wenden Sie sich an den Sponsor / Please refer to primary sponsor

Telephone: **[---]***
Fax: **[---]***
E-mail: **[---]***
URL: **[---]***

Status

- Recruitment Status: **Recruiting ongoing**
- Study Closing (LPLV): **[---]***

Trial Publications, Results and other documents

The parameters in ClinicalTrials.gov and DRKS are not identical. Therefore the data import from ClinicalTrials.gov required adjustments. For full details please see the DRKS FAQs.
- Translation on version: 1
- Last processed date by ClinicalTrials.gov: 2014/02/23

** This entry means the parameter is not applicable or has not been set.*

**** This entry means that data is not displayed due to insufficient data privacy clearing.*