Trial Description

Title

**Efficacy and safety of Sinusitis Hevert SL tablets compared to placebo in adult patients with acute, uncomplicated rhinosinusitis.
A multicenter, randomized, double-blind, placebo-controlled, parallel group phase IV study.**

Trial Acronym

Sinusitis Study

CESAR (Clinical Efficacy of Sinusitis Hevert SL in Acute Rhinitis)

URL of the trial

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Brief Summary in Lay Language

Study to verify the efficacy and tolerability of Sinusitis Hevert SL tablets compared to placebo in adult patients with acute, uncomplicated rhinosinusitis (inflammation of the nasal and paranasal sinuses).

Brief Summary in Scientific Language

**Acute rhinosinusitis is one of the most common diseases worldwide with a prevalence of 6–15% and a large impact on quality of life and socioeconomics. The majority of infections are of viral origin, while acute bacterial infection occurs in only 0.5–2% of cases. Currently available treatment includes a variety of remedies, like analgesic, inhalation with water steam of diluted drugs, nasal douche or spray, decongestant and mucolytic remedies as well as antibiotics.
Sinusitis Hevert SL is registered since 2003 for the treatment of inflammation of the nose and throat region and the sinuses (sinusitis) and contains eleven homeopathic single substances which are classically used in homeopathy for this condition, but has not been evaluated in a randomized controlled clinical trial. In this multicenter, randomized, double-blind, placebo-controlled, parallel group phase IV study the efficacy and safety of Sinusitis Hevert SL tablets compared to placebo in adult patients with acute, uncomplicated rhinosinusitis shall be demonstrated.**

Do you plan to share individual participant data with other researchers?

[---]*

Description IPD sharing plan

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Organizational Data

- DRKS-ID: **DRKS00006877**
- Date of Registration in DRKS: **2014/11/05**
- Date of Registration in Partner Registry or other Primary Registry: **2014/07/07**
- Investigator Sponsored/Initiated Trial (IST/IIT): **no**
- Ethics Approval/Approval of the Ethics Committee: **Approved**
- (leading) Ethics Committee Nr.: **14/0333 - EK 15 , Ethik-Kommission des Landes Berlin**

Secondary IDs

- EudraCT-No.
  (for studies acc. to Drug Law): **2014-000907-29**
- Primary Registry-ID: **EUCTR2014-000907-29-DE (EUCTR)**
- Partner Registry-ID: **NCT02296814 (ClinicalTrials.gov)**

Health condition or Problem studied

- ICD10: **J01 - Acute sinusitis**

Interventions/Observational Groups

- Arm 1: **Sinusitis Hevert SL Tabletten (1st week: 6 times daily 2 tablets and 2nd week: 4 times daily 2 tablets)**
- Arm 2: **Placebo**

Characteristics

- Study Type: **Interventional**
- Study Type Non-Interventional: **[---]***
- Allocation: **Randomized controlled trial**
- Blinding: **[---]***
- Who is blinded: **patient/subject, investigator/therapist, caregiver, assessor**
- Control: **Placebo**
- Purpose: **Treatment**
- Assignment: **Parallel**

Study Type: **Interventional**

Study Type Non-Interventional: **[---]***

Allocation: **Randomized controlled trial**

Blinding: **[---]***

Who is blinded: **patient/subject, investigator/therapist, caregiver, assessor**

Control: **Placebo**

Purpose: **Treatment**

Assignment: **Parallel**

- Phase: **IV**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **N/A**

Primary Outcome

- Rate of responders which occur between baseline and 14 days after baseline (V4). A response is defined as stable reduction of MRSSpat (sum of 5 main rhinosinusitis symptoms daily assessed by the patient) by at least 50%, i.e. reduction by at least 50% and no subsequent change from baseline > –50% up to treatment termination.

- Rate of remissions which occur between baseline and 14 days after baseline (V4). A remission is defined as complete disappearance of all 5 main rhinosinusitis symptoms with no subsequent reoccurrence of any symptom up to treatment termination.

Secondary Outcome

- Time to response
- Time to remission
- Time to improvement in the individual MRSSpat symptoms (in case of positivebaseline value)
- Time to disappearance in the individual MRSSpat symptoms (in case of positive baseline value)
- Change in the overall MRSSinv (sum of 5 main rhinosinusitis symptoms, assessed by the Investigator) at V2 (7 days after baseline), V3 (10 days after baseline) and V4 (14 days after baseline), as well as in the time course of the study
- Change in the overall MRSSinv (sum of the remaining symptoms, assessed by the Investigator) at V2, V3 and V4, as well as in the time course of the study
- Change in the individual MRSSinv symptoms, assessed by the Investigator, between baseline and V2, V3 and V4, as well as in the time course of the study
- Change in the Sino-Nasal Outcome Test, German Adapted Version (SNOT-20 GAV), in the Overall Score (OS) as well as in the sub scores PNS (Primary Nasal Symptoms), SRS (Secondary Rhinogenous Symptoms, and Quality of Life Score (GQOL), assessed by the patient between baseline and V2, V3 and V4
- Change in the SNOT-20 GAV, score of 5 most important symptoms, assessed by the patient between baseline and V2, V3 and V4
- Change in the SNOT-20 GAV, individual symptoms, assessed by the patient between baseline and V2, V3 and V4, respectively
- Change in the assessment of health status by patient using a Visual Analogue

Scale (VASpat) using a 10-cm scale (0= best state of health to 10= worst state of health) between baseline and V2, V3 and V4
- Change in the assessment of the patient's health status by the investigator using a Visual Analogue Scale (VASinv) between baseline and V4
- General assessment of efficacy by the investigator (on a 4-point rating scale) at each visit from V2 to V4
- Use of antibiotics / allowed rescue medication

Countries of recruitment

- DE **Germany**

Locations of Recruitment

- University Medical Center **Charité Immanuel-Krankenhaus (Standort Berlin-Wannsee), Berlin**
- Doctor's Practice **Köln**
- Doctor's Practice **Düren**
- Doctor's Practice **Berlin**
- Doctor's Practice **Leipzig**
- Doctor's Practice **Heidelberg**
- Doctor's Practice **Duisburg**
- Doctor's Practice **Wiesbaden**
- Doctor's Practice **Röthenbach**
- Doctor's Practice **Goch**
- Doctor's Practice **Chemnitz**
- Doctor's Practice **Dresden**
- Doctor's Practice **Wolmirstedt**
- Doctor's Practice **Künzing**
- Doctor's Practice **Essen**
- other **Bochum**
- other **Frankfurt a.M.**
- other **Berlin**
- other **Leipzig**
- Doctor's Practice **Hamburg**
- other **Hamburg**
- Doctor's Practice **Gars am Inn**

- Doctor's Practice **Haag**

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2014/11/24**
- Target Sample Size: **290**
- Monocenter/Multicenter trial: **Multicenter trial**
- National/International: **National**

Inclusion Criteria

- Gender: **Both, male and female**
- Minimum Age: **18 Years**
- Maximum Age: **75 Years**

Additional Inclusion Criteria

1. Signed informed consent
2. Male and female outpatients, aged ≥ 18 and ≤ 75 years
3. Diagnosis of acute, uncomplicated (or recurrent acute) rhinosinusitis
– characterized by Major Rhinosinusitis Symptom Score (MRSSinv) ≥ 8 and ≤ 15 points
– individual score for facial pain/pressure (on bending) ≥ 1 (mild) and ≤ 2 (moderate)
– with presence of symptoms ≤ 3 days prior to inclusion
Out of the 5 main rhinosinusitis symptoms, at least 3 must be present. Among these, the presence of nasal congestion and facial pain / pressure (on bending) is mandatory.
4. Women of childbearing potential: willingness to use contraception methods

Exclusion criteria

Medical history
a) Diseases
1. Chronic rhinosinusitis (i.e. all forms and causes of persistent chronic rhinosinusitis)
2. Polyposis nasi, recent history
3. Infection of dental origin in the maxilla
4. Cystic fibrosis, recent history
5. Anatomical deviations of the nasal septum that significantly impair nasal and paranasal ventilation / air flow
6. Acute symptoms of a known allergic rhinitis
7. History of smoking within the last two years prior to study enrolment or current smoking habits
8. Patients with asthma
9. Known hypersensitivity to study medication or excipients (asteraceae, lactose, allergy to bee venom, etc.)
10. Underlying diseases leading to a significant immune deficiency

11. Signs or symptoms of bacterial sinusitis requiring antibiotic treatment (e.g. fever >38.3°C, orbital complications, severe unilateral frontal headache or toothache)
12. Patients with progressive auto-immune diseases, tuberculosis, leukemia or leukemia-like diseases, multiple sclerosis, inflammatory diseases of the connective tissues, rheumatoid arthritis, Lupus erythematodes, HIV infection or other chronic viral diseases
13. Patients with untreated/unstable thyroid gland disorder (treatment should not include iodine supplementation)
14. Pre-menopausal women (last menstruation ≤ 1 year prior to informed consent) who:
- are nursing or pregnant,
- or are of child-bearing potential and are not practicing an acceptable method of birth control, or do not plan to continue using this method throughout the study. Acceptable methods of birth control include transdermal patch, intra uterine devices/systems (IUDs/IUSs), oral, implantable or injectable contraceptives, double barrier methods, sexual abstinence and vasectomised partner.
15. Severe diseases of liver or kidney
16. Severe somatopathic, neurological and / or psychiatric diseases
17. Patients with malignant growth processes or cancer treatment within the last two years prior to study inclusion.
18. History of alcohol or drug abuse
b) Medication
1. Treatment with systemic or nasal antibiotics or nasal or systemic corticosteroids within the last 4 weeks prior to study inclusion
2. Treatment with alternative medicine preparations (homeopathical and phytotherapeutical drugs) for treatment of common cold like symptoms or with immunomodulating properties (such as Echinacea), within the last 7 days prior to study inclusion
3. Treatment with decongestant (α-sympathomimeticson the day of study inclusion within 5 hours prior to screening and during the study)
4. Chronic use of decongestant remedies
5. Treatment with immunosuppressive medication 8 weeks prior to study inclusion and during the study for any condition
6. Systemic antiviral treatment such as aciclovir; zanamivir, or oseltamivir within 30 days prior to study inclusion
7. Patients requiring antibiotic treatment for any condition at study entry
c) General
1. Parallel participation in any other clinical study or participation in another study within less than 6 weeks prior to study inclusion, or previous participation in this same study
2. Legal incapacity and / or other circumstances rendering the patient unable to understand the nature, scope and possible impact of the study
3. Patients in custody by juridical or official order
4. Patients who have difficulties in understanding the language (German) in which the patient information is given
5. Patients who are employees of a trial center, the CRO, the sponsor or its authorised representatives or are relatives either of the study site staff, the CRO staff; the sponsor staff or its authorised representatives

Addresses

■ **Primary Sponsor**

Hevert-Arzneimittel GmbH & Co. KG

Primary Sponsor

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Sources of Monetary or Material Support

- **Commercial (pharmaceutical industry, medical engineering industry, etc.)**

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Status

- Recruitment Status: **Recruiting complete, follow-up complete**
- Study Closing (LPLV): **2015/04/24**

Trial Publications, Results and other documents

- Paper **[---]***

Please note:
There are additional attributes available concerning this trial. To open an extended view please click here.