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Tonsilotren® in chronic tonsillitis

Submission date
09/01/2013

Recruitment status
No longer recruiting

Registration date
23/01/2013

Overall study status
Completed

Last Edited
09/08/2017

Condition category
Respiratory

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

Plain English summary of protocol

Background and study aims
Chronic tonsillitis is a permanent inflammation of the tonsils. It means recurrent acute throat infections as well as swallowing problems, sore throat and/or bad breath which may come and go. In case of acute throat infections, patients usually receive pain relief medicines and/or antibiotics. Tonsilotren is a homeopathic medicinal product which is traditionally used for tonsillitis. The aim of this study is to assess how well Tonsilotren works in patients with chronic tonsillitis. The effect of Tonsilotren tablets will be assessed when they are given in addition to conventional treatment.

Who can participate?
Patients aged between 6 and 60 with chronic tonsillitis in Germany, Spain and Ukraine

What does the study involve?
Al patients receive conventional treatment which the study doctors adjust to the clinical symptoms of the patients. In addition, one in two patients are randomly allocated to also receive Tonsilotren. Patients see their study doctor 9 times in total over 14 months. At each of the visits, the study doctor performs a thorough physical examination (chronic tonsillitis-specific symptoms as well as respiratory complaints when present). Patients have to take their conventional medication as agreed with the study doctor. The patients belonging to the Tonsilotren group also have to take Tonsilotren according to a fixed dosage scheme. Patients keep a diary to record the changes of their chronic tonsillitis symptoms. In between the visits the study doctors call the patients to check their medical condition.

What are the possible benefits and risks of participating?
Patients receive a conventional symptomatic treatment for their chronic tonsillitis which does not differ from the treatment they would receive if they did not participate in this study. If patients are in the Tonsilotren group, they receive the homeopathic medicinal product Tonsilotren which is usually well tolerated. Possible side effects of Tonsilotren include reactions of hypersensitivity like skin rashes or possibility of increased salivation. At the beginning of this study, patients receive a detailed diagnostic evaluation and are under close medical supervision for as long as the study continues. By participating in this study, patients might contribute to new scientific findings relevant to the treatment of chronic tonsillitis with Tonsilotren.

Where is the study run from?
The study will be carried out by private practices or medical institutions experienced in ear-nose-throat medicine in Germany, Spain and Ukraine

When is the study starting and how long is it expected to run for?
January 2013 to May 2015

Who is funding the study?
Deutsche Homöopathie-Union (Germany)

Who is the main contact?
Dr Jürgen Palm
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
2012-001430-34

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
10-TT-EP-003

Study information

Scientific Title
Therapeutic effectiveness, safety and tolerability of Tonsilotren® tablets in patients (6 to 60 years old) with chronic tonsillitis

Acronym
TocTo

Study objectives

No formal study hypothesis has been formulated. The data will be analyzed exploratively. The actual study has been set up to obtain systematically data of Tonsilotren® when treating patients suffering from chronic tonsillitis with Tonsilotren® under conditions which are as close as possible to normal daily routine.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Germany: The Ethics Committee of the Bavarian State Medical Association (Ethikkommission der Bayrischen Landesärztekammer), 27/08/2012, ref: 12051
2. Spain: The Ethics Committee of the Joined Foundation of the Catalanian Hospitals (Comité Ético de Investigación Clínica de la Fundació unio catalana d'hospitals), 16/10/2012
3. Ukraine:
Local Ethics Committee from the National children's specialized hospital Ohmatdyt (Kiev), 29/08/2012, ref: 48
Local Ethics Committee from the Vinnytsia Regional Clinical Hospital, 30/07/2012, ref: 01-5-02/5
Local Ethics Committee from the Poltava Regional Clinical Hospital, 02/11/2012, ref: 47
Local Ethics Committee from the Odessa National Medical University, 11/09/2012, ref: 1
Local Ethics Committee from the Lugansk Hospital of Ministry of Internal Affairs, 16/07/2012, ref: 1
Local Ethics Committee from the Lugansk Regional Children's Clinical Hospital, 26/07/2012, ref: 1

Study design
Randomized international multicenter open controlled clinical trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
GP practice

Study type(s)
Treatment

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

Health condition(s) or problem(s) studied
Chronic tonsillitis

Interventions
Patients will be observed for 60 weeks. During that time they will receive three treatment cycles with Tonsilotren® each lasting eight weeks, in case the subject will be randomly allocated to the test group. Additionally all study subjects (test as well as control group) receive a symptomatic treatment where needed.

Intervention Type
Drug

Phase
Phase III

Drug/device/biological/vaccine name(s)
Tonsilotren®

Primary outcome measure
Mean period of time between consecutive acute throat infections within one year

Secondary outcome measures
1. Number of days with either sore throat/difficulties in swallowing or halitosis or exhaustion [measurement: documentation in patient's diary]
2. Number of upper respiratory tract infections [measurement: documentation of investigator]
3. Severity of chronic tonsillitis symptoms [measurement: documentation of investigator using a 3-item scale: absent, mild, severe]
4. Frequency of antibiotics consumption due to acute throat infections [measurement: documentation of investigator]
5. Days with analgetics consumption due to acute throat infections [measurement: documentation in patient's diary]
6. Effect of treatment on performance of normal daily activity [measurement: documentation in patient's diary]
7. Patients quality of life [measurement: documentation on 5-item scale: very good, god, moderate, poor, very poor]
8. Treatment outcome according to Integrative Medicine Outcome Scale [measurement: documentation of investigator and patient on 5-item scale: complete recovery, major improvement, slight to moderate improvement, no change, deterioration]
9. Tolerability of treatment [measurement: documentation of investigator and patient on 5-item scale: very good, good, moderate, poor, very poor]
10. Adverse events. [measurement: documentation of investigator]

Overall study start date
30/01/2013

Completion date
30/05/2015

Eligibility

Key inclusion criteria
1. Subjects aged 6 to 60 years, either sex
2. Diagnosis of chronic tonsillitis
3. Written informed consent
4. Willingness and ability to comply with all trial procedures

Participant type(s)
Patient

Age group
Mixed

Sex
Both

Target number of participants
240

Key exclusion criteria
1. Presence of acute throat infection at inclusion
2. Presence of peri-tonsillar abscess
3. Presence of acute and chronic otitis, adenoiditis, sinusitis of all types, odontological infection, bronchial and lung disease, tuberculosis or known allergic manifestations in the throat and / or mouth
4. Obstruction in the pharynx due to enlargement of tonsils
5. Presence of severe cardiovascular, renal or hepatic disease, as well as gastroesophageal reflux, unstable diabetes mellitus, hyperthyroidism, cerebrovascular or other active bleeding, human immunodeficiency virus infection, mononucleosis of each severity, or oropharyngeal gonorrhea
6. History of non-steroidal anti-inflammatory drugs (NSAIDs) intolerance, hematogenetic dysfunction of unknown origin, repeated peptic ulcera or hemorrhages
7. History or presence of all kind of serious streptococcal complications
8. Previous surgery in the past six months or need for surgery of the nose or paranasal sinuses, adenoids and/or tonsils
9. Evidence of any malignant disease during the past five years before enrolment into the trial
10. Presence of neurological and/or psychiatric diseases interfering with evaluation of quality of life and assessment in the patient's diary
11. Treatment with systemic acting antibiotics, glucocorticosteroids or medications with immunomodulating activities during the past four weeks and treatment with NSAIDs as well as locally on the tonsils acting antibiotics, glucocorticosteroids or immuno-modulators during the past week prior to enrolment into the trial
12. Known or suspected hypersensitivity to chromium, mercury or any other ingredient and/or excipient of Tonsilotren, lactose and / or fructose intolerance and known intolerance towards leather and jewelry metals as well as towards dental metal fillings and vaccines;
13. Heavy smoking or known or suspicion to or presence of drug addiction including alcohol abuse
14. Women of childbearing potential without adequate contraception or women, who want to become pregnant, are pregnant or breastfeeding
15. Prior enrolment into this trial
16. Participation in another clinical trial during the past three months prior to enrolment into the trial
17. Incapability of understanding nature, meaning and consequences of the trial
18. Patients in custody by juridical or official order
19. Patients, who are members of the staff of the study center, staff of the sponsor or involved Clinical Research Organizations, the investigator him- / herself or close relatives of the investigator

Date of first enrolment
30/01/2013

Date of final enrolment
30/03/2014

Locations

Countries of recruitment
Germany

Spain

Ukraine

Study participating centre
Rueckersdorfer Str. 61
Roethenbach an der Pegnitz
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D-90552

Sponsor information

Organisation
Deutsche Homöopathie-Union DHU-Arzneimittel GmbH & Co. KG (Germany)

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Sponsor type
Industry

Website
http://www.dhu.com

ROR
https://ror.org/0451ek747

Funder(s)

Funder type
Industry

Funder Name
Deutsche Homöopathie-Union (DHU)-Arzneimittel 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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/08/2017		Yes	No