

Effectiveness of homeopathic treatment (Agraphis nutans 5CH, Thuya occidentalis 5CH, Kalium muriaticum 9CH and Arsenicum iodatum 9CH), as an adjuvant in secretory otitis (SO) in childhood

Submission date 17/10/2012	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 26/02/2013	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 02/08/2016	Condition category Ear, Nose and Throat	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

Secretory otitis, commonly referred to as glue ear, is a childhood condition where fluid (mucus) builds up in the middle ear. This can cause hearing problems and affect the child's social adaptation and academic performance. The mucus can just stay in the ear, can cause a hole to develop in the eardrum (perforated eardrum), or can cause an ear infection (acute otitis media), which would require treatment with antibiotics. The recent guidelines concluded that there is no single effective treatment for secretory otitis, and recommend a period of three months of monitoring during which the secretory otitis may improve spontaneously. If there is no improvement after 3 months, surgical treatment may be required to place tubes (grommets) in the ear to drain the mucus, with or without adenoidectomy (an operation to remove the adenoids). The aim of this study is to assess the effectiveness of homeopathy as an addition to the conventional treatment for children with secretory otitis.

Who can participate?

Children age 2 months to 12 years with secretory otitis

What does the study involve?

Participants are randomly allocated into two groups. One group receives homeopathic treatment and the other group receive a placebo (dummy drug). Both groups also receive conventional treatment (budesonide and ambroxol hydrochloride in an aerosol [spray]) for 20 days at a rate of one session per day.

What are the possible benefits and risks of participating?

Not provided at time of registration

Where is the study run from?
Complejo Hospitalario de Toledo (Spain)

When is the study starting and how long is it expected to run for?
September 2012 to January 2014

Who is funding the study?
University of Zaragoza (Spain)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
2011-006086-17

Protocol serial number
55005646

Study information

Scientific Title
Effectiveness of homeopathic treatment (Agraphis nutans 5CH, Thuya occidentalis 5CH, Kalium muriaticum 9CH and Arsenicum iodatum 9CH), as an adjuvant in secretory otitis (SO) in childhood: a randomized parallel double-blind clinical trial

Study objectives
The coadjuvancy with homeopathy, in patients aged 2 months to 12 years, can improve or resolve the SO, diagnosed through the Bilateral pneumatic otoscopy (OPN), the primary endpoint being a dichotomous one (positive or negative mobility of the tympanic membrane).

Ethics approval required

Old ethics approval format

Ethics approval(s)

RCREC of Toledo, Hospital of Toledo (RCREC of Toledo, Complejo Hospitalario de Toledo), 16/01/2012

Study design

Controlled randomized (1:1) parallel double-blind clinical trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Secretory otitis in childhood

Interventions

Control arm receives

Aerosolot: 1 session / 24 hours / 20 days with: 1 vial of Ambroxol hydrochloride 7.5 mg/ml, 1 vial of budesonide 0.25 mg/ml suspension, and 2cc of physiological saline.

Intervention arm receives aerosol + A or B.

Aerosolot: 1 session / 24 hours / 20 days with: 1 vial of Ambroxol hydrochloride 7.5 mg/ml, 1 vial of budesonide 0.25 mg/ml suspension, and 2cc of physiological saline.

And

Homeopathic:

A: *Agraphis nutans* 5CH (granules) and *Thuya occidentalis* 5CH (granules) 5 granules once a day, preferably in the evening. Approximately 80 pellets are in each tube

or

B: *Kalium muriaticum* 9CH (granules) and *Arsenicum iodatum* 9CH (granules) 5 granules, twice a day. Approximately 80 pellets are in each tube.

Intervention Type

Other

Phase

Not Applicable

Primary outcome(s)

The presence or absence of secretory otitis in childhood depending on the tympanic mobility measured with pneumatic otoscopy

Key secondary outcome(s)

1. Need for surgery (DTT + / - adenoidectomy) in any of the patient's ears with secretory otitis at the end of study to meet the surgical indications of the Spanish Society of Otolaryngology and cervico-facial

2. Number of Secretary Otitis Media, Secretary Otitis Media complicated and tympanic perforations in one of the two ears of patients with secretory otitis during the study period (3 months)
3. Number of days of absence from school or work, the patient or primary caregivers have been forced to make during the study period (3 months) for reasons related to hearing problems (Secretary Otitis Media, Complications of Secretary Otitis Media or perforated eardrum)
4. The proportion and type of intercurrent adverse events will be collected during the trial in both study groups

Completion date

31/01/2014

Eligibility

Key inclusion criteria

1. Age: 2 months - 12 years
2. Informed consent from parents and / or tutors
3. SO diagnosed unilateral or bilateral diagnosed in otolaryngology consultations with pneumatic otoscopy, according to the presence or absence of tympanic mobility. Each ear counted as one unit of primary endpoint.
4. Do not be following any regular treatment, specifically especially corticosteroids, antihistamines and mucolytics

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Child

Lower age limit

2 months

Upper age limit

12 years

Sex

All

Key exclusion criteria

1. Acute Otitis Media or complicated at the time of baseline
2. Have not passed the newborn hearing screenig (OAE)
3. Concomitant diseases
4. Permanent sensorineural hearing loss
5. Autism
6. Down Syndrome craneofaciales or other malformations
7. Malformations of the outer or middle ear
8. Acute Mastoiditis or Cholesteatoma

9. Recent vaccination (less than 30 days)
10. Cilia motility disorders (Kartagener syndrome)
11. Alterations prelingual speech or language
12. Obstructive sleep apnea (OSA)
13. Adenoidectomy
14. Persistence of Tubo-tympanic disease (TTD) or perforated eardrum
15. Lactose intolerance or diabetes (incompatible with placebo and homeopathy)

Date of first enrolment

30/09/2012

Date of final enrolment

31/01/2014

Locations

Countries of recruitment

Spain

Study participating centre

Hospital Virgen de la Salud de Toledo

Toledo

Spain

45071

Sponsor information

Organisation

Individual sponsor (Spain)

Funder(s)

Funder type

University/education

Funder Name

Universidad de Zaragoza

Alternative Name(s)

Saragossa University, School of Zaragoza, University of Zaragoza, Unizar, Universidad Zaragoza, UZ

Funding Body Type

Government organisation

Funding Body Subtype

Universities (academic only)

Location

Spain

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary