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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	[_] Prospectively registered [_] Protocol
Registration date 26/02/2013	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 02/08/2016	**Condition category** Ear, Nose and Throat	[_] Individual participant data [_] 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?
María Fernanda Pedrero Escalas
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
2011-006086-17

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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 Hospitalatio de Toledo), 16/01/2012

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

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 contact María Fernanda Pedrero Escalas [mf.pedrero@gmail.com] to request a patient information sheet

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

Secondary outcome measures
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 Secretory Otitis Media, Secretory 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 (Secretory Otitis Media, Complications of Secretory Otitis Media or perforated eardrum)
4. The proportion and type of intercurrent adverse events will be collected during the trial in both study groups

Overall study start date
30/09/2012

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

Age group
Child

Lower age limit
2 Months

Upper age limit

12 Years

Sex
Both

Target number of participants
220 subjects

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. Cilial 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
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Sponsor information

Organisation

Individual sponsor (Spain)

Sponsor details
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Sponsor type
Other

Funder(s)

Funder type
University/education

Funder Name
Universidad de Zaragoza

Alternative Name(s)
University of Zaragoza, Saragossa University, Universidad Zaragoza, School of Zaragoza, UZ

Funding Body Type
Government organisation

Funding Body Subtype
Universities (academic only)

Location
Spain

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