

# 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

<b>Submission date</b> 17/10/2012	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 26/02/2013	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 02/08/2016	<b>Condition category</b> 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?  
María Fernanda Pedrero Escalas  
mf.pedrero@gmail.com

## Contact information

**Type(s)**  
Scientific

**Contact name**  
Dr María Fernanda Pedrero

**Contact details**  
Hospital Virgen de la Salud de Toledo  
Otorrinology Service  
Av. de Barber, 30  
Toledo  
Spain  
45071  
+34 (0)687 468 806  
mf.pedrero@gmail.com

## 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 Hospitalario 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: *Agropyrum nutans* 5CH (granules) and *Thuja 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

Spain

45071

**Sponsor information**

**Organisation**

Individual sponsor (Spain)

**Sponsor details**

Dr. María Fernanda Pedrero Escalas  
Hospital Virgen de la Salud de Toledo  
Otorrinology Service  
Av. de Barber, 30  
Toledo  
Spain  
45071  
+34 (0)687 468 806  
mf.pedrero@gmail.com

**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