

# Otodolor® eardrops/Otodolor® forte eardrops: a topical treatment of otitis externa

<b>Submission date</b> 08/10/2009	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 22/10/2009	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 03/11/2009	<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**  
Not provided at time of registration

## Contact information

**Type(s)**  
Scientific

**Contact name**  
Prof Dr Andreas Temmel

**Contact details**  
Specialist for ENT Surgery  
KH der Barmherzigen Schwestern  
Stumpergasse 13  
Vienna  
Austria  
A-1060

## Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

**Secondary identifying numbers**  
N/A

## Study information

**Scientific Title**

Safety and efficacy of the homeopathic remedies Otodolor® eardrops/Otodolor® forte eardrops for topical treatment of otitis externa: a non-interventional trial

**Acronym**

OTO1

**Study objectives**

Systematic and prospective data collection on safety and efficacy of homeopathic remedies (Otodolor® eardrops/Otodolor® forte eardrops) for topical treatment of otitis externa in children and adults in the common general practice of ear, nose and throat (ENT) doctors or paediatricians. This trial will assess the following:

1. The reduction of subjective and objective complaints like redness, swelling, eczematous affections, secretion, ear pain and itching
2. The reduction of other otitis externa medications under therapy
3. Safety data (adverse drug reactions [ADRs])

**Ethics approval required**

Old ethics approval format

**Ethics approval(s)**

Submission of a non-interventional study to Regulatory Board/Ethics Committee is not necessary in Austria until after June 2010.

**Study design**

Open longitudinal multicentre non-interventional trial

**Primary study design**

Observational

**Secondary study design**

Multi-centre

**Study setting(s)**

Other

**Study type(s)**

Treatment

**Participant information sheet**

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

**Health condition(s) or problem(s) studied**

Otitis externa

**Interventions**

Otodolor® eardrops (every 2 - 4 hours, 3 - 5 drops/ear) or Otodolor® forte eardrops (every 2 - 4 hours, 3 - 5 drops/ear) for topical treatment of otitis externa over a 2-week period.

**Intervention Type**

Drug

**Phase**

Not Applicable

**Drug/device/biological/vaccine name(s)**

Otodolor® eardrops/Otodolor® forte eardrops

**Primary outcome measure**

1. The reduction of subjective and objective complaints like redness, swelling, eczematous affections, secretion, ear pain and itching
2. The reduction of other otitis externa medications under therapy

**Secondary outcome measures**

Safety assessment (adverse drug reactions [ADRs])

**Overall study start date**

01/09/2008

**Completion date**

01/05/2009

## **Eligibility**

**Key inclusion criteria**

1. Patients with acute or chronic otitis externa presenting to ENT doctors or paediatricians
2. Children aged 6 years onwards and adults (either sex) for Otodolor® eardrops
3. Children aged 12 years onwards and adults (either sex) for Otodolor® forte eardrops

**Participant type(s)**

Patient

**Age group**

Other

**Sex**

Both

**Target number of participants**

196 patients in the common general practice of 20 ENT doctors or paediatricians

**Key exclusion criteria**

1. Patients under the age of 6 years
2. A known or suspected perforation of the eardrum

**Date of first enrolment**

01/09/2008

**Date of final enrolment**

01/05/2009

# Locations

## Countries of recruitment

Austria

## Study participating centre

### Specialist for ENT Surgery

Vienna

Austria

A-1060

# Sponsor information

## Organisation

Dr. Peithner KG nunmehr GmbH & Co (Austria)

## Sponsor details

c/o Dr Felix Kromer

Medical Services Department

Richard Strauss-Str. 13

Vienna

Austria

A-1232

+43 (0)1 616 26 44 64

med.service@peithner.at

## Sponsor type

Industry

## Website

<http://www.peithner.at>

## ROR

<https://ror.org/00wcjzh22>

# Funder(s)

## Funder type

Industry

## Funder Name

## 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