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

Submission date 08/10/2009	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 22/10/2009	**Overall study status** Completed	
Last Edited 03/11/2009	**Condition category** Ear, Nose and Throat	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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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
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Sponsor type
Industry

Website
http://www.peithner.at

ROR
https://ror.org/00wcjzh22

Funder(s)

Funder type
Industry

Funder Name

Dr. Peithner KG nunmehr GmbH & Co (Austria)

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