ISRCTN84220089 https://doi.org/10.1186/ISRCTN84220089

An interventional, randomized, double-blind, placebo-controlled, parallel-assignment, safety /efficacy study for treatment of chronic middle ear infection in adult patients with the antimicrobial peptide OP-145

Submission date 24/09/2007	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol
Registration date 18/01/2008	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 18/01/2008	**Condition category** Ear, Nose and Throat	[_] Individual participant data [_] Record updated in last year

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
P02.216

Study information

Scientific Title

Acronym
OP-145

Study objectives
The purpose of this study is to determine the safety, tolerability, and efficacy of OP-145 eardrops to the middle ear of patients with chronic otitis media. We hypothesize that OP-145 will improve the middle ear mucosa in patients with chronic otitis media.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Medical Ethics Committee of the Leiden University Medical Center. Approved on the 19th December 2003 (Ref: P02.216/YR/yr)

Study design
Phase I/II, double-blind, parallel-assignment, safety/efficacy, randomized placebo-controlled trial.

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Not Specified

Participant information sheet

Health condition(s) or problem(s) studied
Chronic otitis media

Interventions
Part I dose finding study:

The participants were allocated into four trial arms in the order of inclusion timepoints i.e. the first four participants were allocated to the lowest dose group, second four in the next dose group, etc.

Arm 1: 0.25 mg/ml OP-145 eardrops twice a day
Arm 2: 0.5 mg/ml OP-145 eardrops twice a day
Arm 3: 1.0 mg/ml OP-145 eardrops twice a day
Arm 4: 2.0 mg/ml OP-145 eardrops twice a day

Duration of intervention: 2 weeks

Part II randomised controlled study:
Based on the results of the Part I study the Part II study was executed with 0.5 mg/ml OP-145 eardops twice a day (control: placebo twice a day) for 2 weeks.

Intervention Type
Other

Phase
Phase I/II

Primary outcome measure
Safety of OP-145 eardrops, which will be determined by the following at baseline and week 1, 2, 4, 8, and 12 (for both Part I and II of the trial):
1. Hearing levels
2. Blood analysis
3. Antibody detection
4. Bacterial culture of ear and throat swabs
5. Quality of life questionnaires (the 36-item Short Form health survey (SF-36), the Brief Illness Perception Questionnaire and the Chronic Ear Survey)

Secondary outcome measures
Efficacy of OP-145 eardrops, assessed by the following at baseline and week 1, 2, 4, 8, and 12:
1. Mucosal endoscopic scores (for both Part I and II of the trial)
2. Quality of life questionnaires (the 36-item Short Form health survey (SF-36), the Brief Illness Perception Questionnaire and the Chronic Ear Survey) (only for Part II of the trial)

Overall study start date
01/03/2004

Completion date
01/04/2008

Eligibility

Key inclusion criteria
Inclusion criteria for the Part I dose finding study:
1. Adults >= 18 years, males and females
2. Legally competent, no psychiatric history
3. Chronic otitis media with a clear perforation of the tympanic membrane >3 months
4. Chronic proliferative mucosal changes (confirmed by Computerised Tomography (CT) scan)
5. Antibiotic therapy resistant (Adequately treated with at least 2 different eardrops for >6 weeks)

Inclusion criteria for the Part II randomised controlled study:
1. Adults, both males and females, over 18 years of age
2. Legally competent, with no history of psychiatric disorders
3. Chronic otitis media with a clear perforation of the tympanic membrane, lasting longer than 6 months
4. Chronic proliferative mucosal changes (confirmed with CT scan)
5. Antibiotic therapy resistant (Adequately treated with at least 2 different eardrops for >6 weeks)

Participant type(s)
Patient

Age group
Not Specified

Sex
Not Specified

Target number of participants
Part I: 16 patients; Part II: 52, with an interim analysis after 26 patients.

Key exclusion criteria
Exclusion criteria for the Part I dose finding study:
1. Presence of cholesteatoma in the treated ear (confirmed with CT-scan)
2. History of mastoidectomy in the treated ear (resulting in a 'radicaalholte')
3. Pregnant and breastfeeding women
4. Patients that have been using topical, oral or parenteral antibiotics or steroids in the last 30 days
5. Patients that have been using prednison or any other immunosuppressive agent in the last 30 days
6. Patients with serious headaches
7. Patients with Down syndrome or other congenital anomalies in the upper respiratory tract
8. Immunocompromized patients or patients with auto-immune disorders
9. History of seizures
10. Patients with deficits at the nervus facialis

Exclusion criteria for the Part II randomised controlled study:
1. Presence of cholesteatoma in the treated ear (confirmed with CT-scan)
2. History of mastoidectomy in the treated ear (resulting in a 'radicaalholte')
3. Pregnant and breastfeeding women
4. Patients that have been using topical, oral or parenteral antibiotics or steroids in the last 30 days
5. Patients that have been using prednison or any other immunosuppressive agent in the last 30 days
6. Patients with serious headaches
7. Patients with Down syndrome or other congenital anomalies in the upper respiratory tract
8. Immunocompromized patients or patients with auto-immune disorders
9. History of seizures
10. Patients with deficits at the nervus facialis
11. Patients who were included in the Part I dose finding study

Date of first enrolment
01/03/2004

Date of final enrolment
01/04/2008

Locations

Countries of recruitment
Netherlands

Study participating centre
Leiden University Medical Center
Leiden
Netherlands
2333 ZA

Sponsor information

Organisation
OctoPlus N.V. (The Netherlands)

Sponsor details
c/o Dr Ewoud-Jan van Hoogdalem
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Sponsor type
Industry

Website
http://www.octoplus.nl/index.cfm/site/OctoPlus/pageid/821DEDEC-E30E-0D4E-CC80F8CDD400753F/index.cfm

ROR
https://ror.org/01dn4wg45

Funder(s)

Funder type
Industry

Funder Name
OctoPlus Inc. (The Netherlands)

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