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Treatment of chronic suppurative otitis media with the antimicrobial peptide OP-145 (AMP60.4Ac) in adults

Submission date	Recruitment status	[_] Prospectively registered
13/10/2015	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
14/10/2015	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
07/11/2023	Ear, Nose and Throat	

Plain English summary of protocol

Background and study aims
Chronic suppurative otitis media (CSOM) is a long-lasting infection of the middle ear. The middle ear, also known as the tympanic cavity, is the name given to the air-filled space directly behind the ear drum. In CSOM, an infection leads to long-lasting irritation of this area causing pus to continually drain from the ear (suppuration) and even hearing loss in the affected ear. The first line treatment for CSOM is the use of antibiotics, which work to fight the infection. When antibiotics are used a lot, bacteria can become resistant to their effects, which make them much more difficult to treat. OP-145 is a new product which has been shown to be effective against harmful microorganisms and to reduce inflammation. The aim of this study is to find out whether OP-145-containing ear drops are an effective and safe treatment for CSOM in adults.

Who can participate?
Adults with chronic suppurative otitis media which is resistant to antibiotic treatment.

What does the study involve?
Participants are randomly allocated to one of two groups. Those in the first group are given OP-145 ear drops to use twice a day for two weeks. Those in the second group are given placebo (inactive medication) ear drops to use twice a day for two weeks. Participants in both groups are asked to attend a clinic at the start of the study and then again after 1, 2, 4, 8 and 12 weeks so that their ears can be examined to find out whether the ear drops have helped with treatment or have had any unwanted side effects.

What are the possible benefits and risks of participating?
Not provided at time of registration.

Where is the study run from?
Leiden University Medical Center (lead center) and six other medical centres in the Netherlands.

When is the study starting and how long is it expected to run for?
September 2006 to July 2007

Who is funding the study?
OctoPlus BV (Netherlands)

Who is the main contact?
1. Dr Peter Nibbering (Scientific)
2. Dr Nanno Peek (Scientific)

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
P02.216

Study information

Scientific Title
Treatment of chronic suppurative otitis media with the antimicrobial peptide OP-145 (AMP60.4Ac) in adults

Study objectives
The aim of this study is to investigate the safety and efficacy of ear drops containing OP-145 in adults with chronic suppurative otitis media (CSOM).

Ethics approval required
Old ethics approval format

Ethics approval(s)
Independent Ethics Committee of the Leiden University Medical Center, 20/06/2008, ref: P02-216

Study design
Randomized double-blind placebo-controlled multi-centre phase 2 study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

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

Interventions
Participants are randomly allocated to one of two groups. The first group receive the OP-145, reconstituted in eardrops at a concentration of 0.5 mg/ml, and the second group receive control ear drops which do not contain OP-145. Participants are asked to apply a few drops (± 100 µl) directly on the tympanic membrane, twice daily for 2 weeks, followed by 10 weeks follow-up.

Intervention Type
Drug

Phase

Phase II

Drug/device/biological/vaccine name(s)
OP-145

Primary outcome measure
Safety of the OP-145 was determined by recording adverse effects and concomitant medication, laboratory tests (specific peptide antibodies and general hematology), swabs from the middle ear and throat for bacterial culture and audiometry (including high pitch audiometry) at baseline 1, 2, 4, 8 and 12 weeks.

Secondary outcome measures
1. Efficacy of the OP-145 in inducing improvement in the mucosa of the middle ear of adults with CSOM is measured by otoscopic inspections at baseline 1, 2, 4, 8 and 12 weeks.
2. Quality of life is determined using he SF-36, the chronic ear survey (CES) and the Brief Illness Perception Questionnaire (IPQ-b) at baseline 1, 2, 4, 8 and 12 weeks.

Overall study start date
19/09/2006

Completion date
04/07/2008

Eligibility

Key inclusion criteria
1. Aged 18 years or older
2. Legally competent, no psychiatric history
3. Diagnosis of CSOM with chronic proliferative mucosal changes > 6 months
4. A clear perforation of the tympanic membrane to allow proper inspection of the middle ear mucosa
5. Antibiotic therapy resistant (having received adequate treatment for CSOM for at least 2 periods of in total ≥ 6 weeks within the past year with at least two different ear drops and the last treatment period having occurred within the last 6 months before screening)

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
52 subjects

Total final enrolment
50

Key exclusion criteria
1. Cholesteatoma in the ear to be treated (i.e. CSOM with cholesteatoma)
2. Presence of a radical cavity in the ear to be treated
3. Use of systemic immune suppressants or antibiotics, use of topical antibiotics, corticosteroids or other eardrops in one of the ears until 4 weeks before study start
4. Down's syndrome or other congenital anomalies to the external or middle ear or to the area of the "Eustachian tube – middle ear" of the ear to be treated
5. Presence of immune disorders, e.g. primary immune deficiency, immune proliferative disorders, Multiple Sclerosis, Crohn's Disease, rheumatoid arthritis or Primary Ciliary Dyskinesia
6. Severe dizziness or severe headache, impacting on subjects' daily life activities
7. Facialis nerve disorders on the side of the ear to be treated
8. Pregnancy, the wish to become pregnant or to breastfeed during the study, or, in case of a male subject, the wish to make his partner pregnant during the study
9. Prior participation in the dose-finding study of the program

Date of first enrolment
19/09/2006

Date of final enrolment
15/04/2008

Locations

Countries of recruitment
Netherlands

Study participating centre
Leiden University Medical Center
Dept ENT
Albinusdreef 2
Leiden
Netherlands
2333 ZA

Study participating centre
Erasmus Medical Center
's-Gravendijkwal 230
Rotterdam
Netherlands
3015 CE

Study participating centre

VU University Medical Center
De Boelelaan 1118
Amsterdam
Netherlands
1081 HZ

Study participating centre
West Frieze Hospital (Westfriesgasthuis)
Maelsonstraat 3
Hoorn
Netherlands
1624 NP

Study participating centre
Alkmaar Medical Center
Wilhelminalaan 12
Alkmaar
Netherlands
1815 JCL

Study participating centre
St. Elisabeth Hospital
Hilvarenbeekse Weg 60
Tilburg
Netherlands
5022 GC

Study participating centre
Wilhelmina Hospital
Europaweg-Zuid 1
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Netherlands
9401 RK

Sponsor information

Organisation
OctoPlus BV

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Sponsor type
Industry

Website
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ROR
https://ror.org/01dn4wg45

Funder(s)

Funder type
Industry

Funder Name
OctoPlus BV

Results and Publications

Publication and dissemination plan
A poster (L1-3337) on the results of this study has been presented at ICAAC 2009.
In addition, publication an open-access international journal is planned as soon as possible.

Intention to publish date
01/12/2015

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		14/04/2020	12/05/2021	Yes	No
Protocol (other)		14/04/2020	07/11/2023	No	No