

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

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<b>Registration date</b> 14/10/2015	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 07/11/2023	<b>Condition category</b> Ear, Nose and Throat	<input type="checkbox"/> Individual participant data

## 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

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Scientific

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## Additional identifiers

**Clinical Trials Information System (CTIS)**  
Nil known

**Protocol serial number**  
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

**Study type(s)**

Treatment

**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 ( $\pm 100 \mu\text{l}$ ) 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(s)**

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.

**Key secondary outcome(s))**

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 the SF-36, the chronic ear survey (CES) and the Brief Illness Perception Questionnaire (IPQ-b) at baseline 1, 2, 4, 8 and 12 weeks.

**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  $\geq 6$  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

**Healthy volunteers allowed**

No

**Age group**

Adult

**Lower age limit**

18 years

**Sex**

All

**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

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5022 GC

**Study participating centre****Wilhelmina Hospital**

Europaweg-Zuid 1

Assen

Netherlands

9401 RK

## Sponsor information

**Organisation**

OctoPlus BV

**ROR**

<https://ror.org/01dn4wg45>

## Funder(s)

**Funder type**

Industry

**Funder Name**

OctoPlus BV

# Results and Publications

## 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?
<a href="#">Results article</a>		14/04/2020	12/05/2021	Yes	No
<a href="#">Protocol (other)</a>		14/04/2020	07/11/2023	No	No