



## Clinical trial results:

## Novel Imaging of the Eustachian Tube, a CT study using dilute iodixanol in an adult population

### Summary

EudraCT number	2014-003614-87
Trial protocol	NO
Global end of trial date	30 June 2017

### Results information

Result version number	v1 (current)
This version publication date	03 July 2021
First version publication date	03 July 2021
Summary attachment (see zip file)	Published article (Pasientstudien.pdf)

### Trial information

#### Trial identification

Sponsor protocol code	ET31068
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#### Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT02282540
WHO universal trial number (UTN)	-

Notes:

### Sponsors

Sponsor organisation name	Oslo University Hospital
Sponsor organisation address	Sognsvannsveien 20, Oslo, Norway, 0424
Public contact	Dep. of Radiology and Nuclear Med., Oslo University Hospital, Rikshospitalet, ehopp@ous-hf.no
Scientific contact	Dep. of Radiology and Nuclear Med., Oslo University Hospital, Rikshospitalet, ehopp@ous-hf.no

Notes:

### Paediatric regulatory details

Is trial part of an agreed paediatric investigation plan (PIP)	No
Does article 45 of REGULATION (EC) No 1901/2006 apply to this trial?	No
Does article 46 of REGULATION (EC) No 1901/2006 apply to this trial?	No

Notes:

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**Results analysis stage**

Analysis stage	Final
Date of interim/final analysis	31 December 2017
Is this the analysis of the primary completion data?	No
Global end of trial reached?	Yes
Global end of trial date	30 June 2017
Was the trial ended prematurely?	No

Notes:

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**General information about the trial**

Main objective of the trial:

To diagnose dysfunction in the eustachian tube by injecting an iodine based contrast medium into the middle ear followed by CT imaging

Protection of trial subjects:

Calm examination environment. thorough information. Local anesthesia. Follow up

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	01 May 2015
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	No

Notes:

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**Population of trial subjects**

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**Subjects enrolled per country**

Country: Number of subjects enrolled	Norway: 23
Worldwide total number of subjects	23
EEA total number of subjects	23

Notes:

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**Subjects enrolled per age group**

In utero	0
Preterm newborn - gestational age < 37 wk	0
Newborns (0-27 days)	0
Infants and toddlers (28 days-23 months)	0
Children (2-11 years)	0
Adolescents (12-17 years)	0
Adults (18-64 years)	23
From 65 to 84 years	0
85 years and over	0

## Subject disposition

### Recruitment

Recruitment details:

Adults. OME diagnosis seeking treatment 2015-2017. Living in Southern Norway

Controls: adults, healthy middle ears

### Pre-assignment

Screening details:

Adult patients with OME who were subject for balloon dilation of the Eustachian tube. no known allergies towards contrast media

Controls chosen from a mb Meniere group because they were subject for middle ear drainage

### Pre-assignment period milestones

Number of subjects started	23
Number of subjects completed	23

### Period 1

Period 1 title	pre procedure clinical examination
Is this the baseline period?	No
Allocation method	Not applicable
Blinding used	Not blinded

### Arms

Are arms mutually exclusive?	Yes
<b>Arm title</b>	patient group

Arm description:

Patients With OME referred for Balloon dilation. Inclusion.

Arm type	No intervention
No investigational medicinal product assigned in this arm	
<b>Arm title</b>	control group

Arm description:

mb meniere patients who were thought to benefit from tympanostomy

Arm type	No intervention
No investigational medicinal product assigned in this arm	

Number of subjects in period 1	patient group	control group
Started	18	5
Completed	18	5

**Period 2**

Period 2 title	Procedure
Is this the baseline period?	Yes <sup>[1]</sup>
Allocation method	Not applicable
Blinding used	Not blinded

**Arms**

Are arms mutually exclusive?	Yes
<b>Arm title</b>	Patient group

Arm description:

OME patients

Arm type	Experimental
Investigational medicinal product name	Visipaque
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection/infusion
Routes of administration	Intratympanic use

Dosage and administration details:

a 20% iodixanol (Visipaque<sup>TM</sup> 320 mg/mL) solution diluted with saline (NaCl 9 mg/mL), was slowly injected into the middle ear through the tympanostomy tube using a 22-G suction needle until the middle ear was filled up, but not expanded. The amount given was approximately 0.5 ml.

<b>Arm title</b>	Control group
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Arm description:

Mb Meniere, no middle ear disease

Arm type	Active comparator
Investigational medicinal product name	Visipaque
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection/infusion
Routes of administration	Intratympanic use

Dosage and administration details:

a 20% iodixanol (Visipaque<sup>TM</sup> 320 mg/mL) solution diluted with saline (NaCl 9 mg/mL), was slowly injected into the middle ear through the tympanostomy tube using a 22-G suction needle until the middle ear was filled up, but not expanded. The amount given was approximately 0.5 ml.

Notes:

[1] - Period 1 is not the baseline period. It is expected that period 1 will be the baseline period.

Justification: Period 1 is the inclusion period without intervention. The Product was given only once in period 2 in both arms

<b>Number of subjects in period 2</b>	Patient group	Control group
Started	18	5
Completed	17	5
Not completed	1	0
Protocol deviation	1	-

<b>Period 3</b>	
Period 3 title	Four -six month follow up
Is this the baseline period?	No
Allocation method	Not applicable
Blinding used	Not blinded
<b>Arms</b>	
Are arms mutually exclusive?	Yes
<b>Arm title</b>	Patient group
Arm description: follow up of OME patients	
Arm type	No intervention
No investigational medicinal product assigned in this arm	
<b>Arm title</b>	Control group
Arm description: mb Meniere	
Arm type	No intervention
No investigational medicinal product assigned in this arm	

Number of subjects in period 3	Patient group	Control group
Started	17	5
Completed	17	5

## Baseline characteristics

### Reporting groups

Reporting group title	Procedure
Reporting group description: -	

Reporting group values	Procedure	Total	
Number of subjects	23	23	
Age categorical			
Units: Subjects			
In utero	0	0	
Preterm newborn infants (gestational age < 37 wks)	0	0	
Newborns (0-27 days)	0	0	
Infants and toddlers (28 days-23 months)	0	0	
Children (2-11 years)	0	0	
Adolescents (12-17 years)	0	0	
Adults (18-64 years)	23	23	
From 65-84 years	0	0	
85 years and over	0	0	
Age continuous			
Units: years			
arithmetic mean	50		
full range (min-max)	18 to 64	-	
Gender categorical			
Units: Subjects			
Female	12	12	
Male	11	11	

## End points

### End points reporting groups

Reporting group title	patient group
Reporting group description: Patients With OME referred for Balloon dilation. Inclusion.	
Reporting group title	control group
Reporting group description: mb meniere patients who were thought to benefit from tympanostomy	
Reporting group title	Patient group
Reporting group description: OME patients	
Reporting group title	Control group
Reporting group description: Mb Meniere, no middle ear disease	
Reporting group title	Patient group
Reporting group description: follow up of OME patients	
Reporting group title	Control group
Reporting group description: mb Meniere	

### Primary: Contrast medium passage

End point title	Contrast medium passage <sup>[1]</sup>
End point description: Visual assessment at CT examination	
End point type	Primary
End point timeframe: 10 minutes after contrast medium administration	

Notes:

[1] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: Study number was too small for statistical analysis in this feasibility study

End point values	Patient group	Control group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	14 <sup>[2]</sup>	5		
Units: individuals				
Cartilaginous Eustachian tube	2	2		
Bony Eustachian tube	8	0		
Epipharynx	4	3		

Notes:

[2] - three did not have passage to the Eustachian tube at all, and one was excluded

### Statistical analyses

No statistical analyses for this end point

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**Secondary: Middle ear inflammation**

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End point title	Middle ear inflammation
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End point description:

Mucous membrane inspection by otoscopy

End point type	Secondary
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End point timeframe:

At time of contrast medium administration, four-six months after administration

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End point values	Patient group	Control group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	17	5		
Units: individuals				
inflammation	0	0		
no inflammation	17	5		

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**Statistical analyses**

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No statistical analyses for this end point



## Adverse events

### Adverse events information

Timeframe for reporting adverse events:

2015-2017

Adverse event reporting additional description:

clinical observation and patient reporting

Assessment type	Systematic
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### Dictionary used

Dictionary name	MedDRA
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Dictionary version	20.1
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### Reporting groups

Reporting group title	Patient group
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Reporting group description:

OME patients subject to contrast medium administration in the middle ear

Reporting group title	Control group
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Reporting group description:

Control group subject to contrast medium administration in the middle ear

Serious adverse events	Patient group	Control group	
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 18 (0.00%)	0 / 5 (0.00%)	
number of deaths (all causes)	0	0	
number of deaths resulting from adverse events	0	0	

Frequency threshold for reporting non-serious adverse events: 4 %

Non-serious adverse events	Patient group	Control group	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	0 / 18 (0.00%)	1 / 5 (20.00%)	
Ear and labyrinth disorders			
Dizziness	Additional description: One of the control patients reported transient dizziness during CM administration. Dizziness was classified as an expected AE in the study protocol. The symptoms resolved before the examination was over for this particular patient and we assumed		
subjects affected / exposed	0 / 18 (0.00%)	1 / 5 (20.00%)	
occurrences (all)	0	1	

## More information

### Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? No

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### Interruptions (globally)

Were there any global interruptions to the trial? No

### Limitations and caveats

Limitations of the trial such as small numbers of subjects analysed or technical problems leading to unreliable data.

Low number of inclusion in both arms. Audiometry not part of the study
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Notes:

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### Online references

<http://www.ncbi.nlm.nih.gov/pubmed/32030198>