



## Clinical trial results: Safety and Efficacy Evaluation of Topical Moxidex Otic Solution in the Treatment of Acute Otitis Externa (AOE)

### Summary

EudraCT number	2018-000641-39
Trial protocol	Outside EU/EEA
Global end of trial date	25 July 2007

### Results information

Result version number	v1 (current)
This version publication date	08 August 2018
First version publication date	08 August 2018

### Trial information

#### Trial identification

Sponsor protocol code	C-05-37
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#### Additional study identifiers

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

Notes:

### Sponsors

Sponsor organisation name	Alcon Research Ltd
Sponsor organisation address	6201 S. Freeway, Fort Worth, TX, United States, 76134
Public contact	Ophthalmology Unit, Novartis Pharmaceuticals , + 44 0127666733385, linda.masson@novartis.com
Scientific contact	Ophthalmology Unit, Novartis Pharmaceuticals , + 44 0127666733385, linda.masson@novartis.com

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?	Yes

Notes:

## Results analysis stage

Analysis stage	Final
Date of interim/final analysis	25 July 2007
Is this the analysis of the primary completion data?	Yes
Primary completion date	25 July 2007
Global end of trial reached?	Yes
Global end of trial date	25 July 2007
Was the trial ended prematurely?	No

Notes:

## General information about the trial

Main objective of the trial:

The purpose of this study was to evaluate the efficacy and safety of topical Moxidex solution for the treatment of acute otitis externa (AOE).

Protection of trial subjects:

Prior to the start of the study, the study protocol, the informed consent and assent documents, patient instruction sheets, the Investigator's Brochure, as well as any advertising materials used to recruit patients were submitted to institutional review boards (IRBs) and independent ethics committees (IECs). The IRB/IECs reviewed all documents and approved required documents; copies of the approval letters were provided to Alcon. Consistent with both the IRB/IEC's requirements and all applicable regulations, the Investigators periodically provided study updates to the IRB/IEC. A patient or parent/legal guardian (if necessary, a legally authorized representative) provided informed consent, and children signed an approved assent form when appropriate. This study was conducted in accordance with Good Clinical Practices (GCP) and the ethical principles that have their origins in the Declaration of Helsinki.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	26 June 2006
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	No

Notes:

## Population of trial subjects

### Subjects enrolled per country

Country: Number of subjects enrolled	United States: 268
Worldwide total number of subjects	268
EEA total number of subjects	0

Notes:

### 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)	74

Adults (18-64 years)	181
From 65 to 84 years	12
85 years and over	1

## Subject disposition

### Recruitment

Recruitment details:

Subjects were recruited from 40 study centers located in the United States.

### Pre-assignment

Screening details:

This reporting group includes all subjects who received drug (Intent-to-Treat (ITT) Analysis Set).

### Period 1

Period 1 title	Overall (overall period)
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Investigator, Subject

### Arms

Are arms mutually exclusive?	Yes
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<b>Arm title</b>	Moxidex solution
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Arm description:

Moxifloxacin 0.5%/dexamethasone phosphate 0.1% solution, 4 drops twice daily (morning and evening), for 7 days

Arm type	Experimental
Investigational medicinal product name	moxifloxacin 0.5%/dexamethasone phosphate 0.1% solution
Investigational medicinal product code	
Other name	Moxidex
Pharmaceutical forms	Ear drops, solution
Routes of administration	Auricular use

Dosage and administration details:

4 drops BID for 7 days

<b>Arm title</b>	Moxifloxacin Solution
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Arm description:

Moxifloxacin hydrochloride 0.5% solution, 4 drops twice daily (morning and evening), for 7 days

Arm type	Active comparator
Investigational medicinal product name	Moxifloxacin hydrochloride 0.5% solution
Investigational medicinal product code	
Other name	Moxifloxacin
Pharmaceutical forms	Ear drops, solution
Routes of administration	Auricular use

Dosage and administration details:

4 drops BID for 7 days

<b>Number of subjects in period 1</b>	Moxidex solution	Moxifloxacin Solution
Started	131	137
Completed	115	121
Not completed	16	16
Treatment failure	5	7
Adverse event, non-fatal	6	5
Inclusion/exclusion violation	2	-
Other	1	-
Decision unrelated to an AE	1	2
Lost to follow-up	-	2
Noncompliance	1	-

## Baseline characteristics

### Reporting groups

Reporting group title	Moxidex solution
Reporting group description: Moxifloxacin 0.5%/dexamethasone phosphate 0.1% solution, 4 drops twice daily (morning and evening), for 7 days	
Reporting group title	Moxifloxacin Solution
Reporting group description: Moxifloxacin hydrochloride 0.5% solution, 4 drops twice daily (morning and evening), for 7 days	

Reporting group values	Moxidex solution	Moxifloxacin Solution	Total
Number of subjects	131	137	268
Age categorical			
ITT Analysis Set.			
Units: Subjects			
Adolescents (12-17 years)	35	39	74
Adults (18-64 years)	88	93	181
From 65-84 years	8	4	12
85 years and over	0	1	1
Gender categorical			
Units: Subjects			
Female	66	73	139
Male	65	64	129

## End points

### End points reporting groups

Reporting group title	Moxidex solution
Reporting group description: Moxifloxacin 0.5%/dexamethasone phosphate 0.1% solution, 4 drops twice daily (morning and evening), for 7 days	
Reporting group title	Moxifloxacin Solution
Reporting group description: Moxifloxacin hydrochloride 0.5% solution, 4 drops twice daily (morning and evening), for 7 days	

### Primary: Time to complete relief of ear pain

End point title	Time to complete relief of ear pain
End point description: Complete relief of ear pain was defined as occurring on the first day that ear pain was completely relieved and remained completely relieved for all subsequent diary entries. Subject reported ear pain relief was assessed twice daily using an interactive voice recognition phone-in diary system (IVRS) and graded on a scale of 0 (complete relief of ear pain) to 6 (very much worsening of ear pain). This analysis set included all subjects who received drug, met pre-randomization inclusion and exclusion criteria and were pathogen positive for bacteria on Day 1 (Modified ITT (MITT) Analysis Set).	
End point type	Primary
End point timeframe: Up to Day 11 (Test of Cure (TOC))	

End point values	Moxidex solution	Moxifloxacin Solution		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	127	129		
Units: units on a scale				
median (confidence interval 95%)	7.0 (6.50 to 8.00)	7.0 (6.00 to 9.00)		

### Statistical analyses

Statistical analysis title	Time to complete relief of ear pain
Comparison groups	Moxifloxacin Solution v Moxidex solution
Number of subjects included in analysis	256
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.5511
Method	Logrank

### Secondary: Percentage of subjects with clinical cure

End point title	Percentage of subjects with clinical cure
End point description: A clinical response of resolved/cured as evaluated by the Investigator at Visit 4 was considered a clinical cure. MITT Analysis Set.	
End point type	Secondary
End point timeframe: Day 11 (TOC)	

<b>End point values</b>	Moxidex solution	Moxifloxacin Solution		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	127	129		
Units: percentage of subjects				
number (not applicable)	85.0	82.2		

### Statistical analyses

<b>Statistical analysis title</b>	Clinical Cure
Comparison groups	Moxidex solution v Moxifloxacin Solution
Number of subjects included in analysis	256
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.5354
Method	Chi-squared

### Secondary: Percentage of subjects for microbiological outcome

End point title	Percentage of subjects for microbiological outcome
End point description: The eradication of pre-therapy pathogens was assessed at the TOC visit. Bacterial response (success or failure) was calculated. MITT Analysis Set.	
End point type	Secondary
End point timeframe: Day 11 (TOC)	

<b>End point values</b>	Moxidex solution	Moxifloxacin Solution		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	127	129		
Units: percentage of subjects				
number (not applicable)				
Success	85.0	82.2		
Failure	15.0	17.8		

### Statistical analyses

<b>Statistical analysis title</b>	Microbiological outcome - Treatment Failure
Comparison groups	Moxidex solution v Moxifloxacin Solution
Number of subjects included in analysis	256
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.5354
Method	Chi-squared

### Secondary: Percentage of subjects with treatment failure

End point title	Percentage of subjects with treatment failure
End point description:	Subjects who had no clinically relevant response to the medication or whose symptoms worsened after at least 2 full days of treatment with the study medication could be considered "treatment failures." MITT Analysis Set.
End point type	Secondary
End point timeframe:	Day 11 (TOC)

<b>End point values</b>	Moxidex solution	Moxifloxacin Solution		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	127	129		
Units: percentage of subjects				
number (not applicable)	15.0	17.8		

### Statistical analyses

<b>Statistical analysis title</b>	Treatment failure
Comparison groups	Moxidex solution v Moxifloxacin Solution
Number of subjects included in analysis	256
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.5354
Method	Chi-squared



## Adverse events

### Adverse events information<sup>[1]</sup>

Timeframe for reporting adverse events:

Adverse events (AEs) are collected from First Patient First Visit (FPFV) until Last Patient Last Visit (LPLV). All adverse events reported in this record are from date of First Patient First Treatment until Last Patient Last Visit.

Adverse event reporting additional description:

This analysis population includes all subjects who received study drug (Safety Analysis Set). Only total subjects affected by non-serious AEs that occurred at >5% are reported.

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	Moxidex solution
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Reporting group description:

Moxifloxacin 0.5%/dexamethasone phosphate 0.1% solution, 4 drops twice daily (morning and evening), for 7 days

Reporting group title	Moxifloxacin Solution
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Reporting group description:

Moxifloxacin hydrochloride 0.5% solution, 4 drops twice daily (morning and evening), for 7 days

<b>Serious adverse events</b>	Moxidex solution	Moxifloxacin Solution	
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 131 (0.00%)	0 / 137 (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: 5 %

<b>Non-serious adverse events</b>	Moxidex solution	Moxifloxacin Solution	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	0 / 131 (0.00%)	0 / 137 (0.00%)	

Notes:

[1] - There are no non-serious adverse events recorded for these results. It is expected that there will be at least one non-serious adverse event reported.

Justification: No non-serious adverse events occurred above the 5% threshold.

## **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**

None reported