



Clinical trial results:

An Evaluation of the Safety and Efficacy of Moxifloxacin Ophthalmic Solution 0.5% Versus Ofloxacin Ophthalmic Solution 0.3% in the Treatment of Bacterial Conjunctivitis in Chinese Patients

Summary

EudraCT number	2017-002727-24
Trial protocol	Outside EU/EEA
Global end of trial date	15 April 2014

Results information

Result version number	v1 (current)
This version publication date	08 December 2017
First version publication date	08 December 2017

Trial information

Trial identification

Sponsor protocol code	C-10-051
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Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT01573910
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Alcon Research
Sponsor organisation address	6201 S. Freeway, Fort Worth, United States, 76134
Public contact	Ophthalmology Unit, Novartis Pharmaceuticals, +44 01276 6673 3391, dennis.wong@novartis.com
Scientific contact	Ophthalmology Unit, Novartis Pharmaceuticals, +44 01276 6673 3391, dennis.wong@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	15 April 2014
Is this the analysis of the primary completion data?	Yes
Primary completion date	15 April 2014
Global end of trial reached?	Yes
Global end of trial date	15 April 2014
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The purpose of this study is to evaluate Moxifloxacin 0.5% relative to Ofloxacin 0.3% in the treatment of bacterial conjunctivitis in Chinese patients.

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	02 May 2012
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	Yes

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	China: 982
Worldwide total number of subjects	982
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)	17
Adolescents (12-17 years)	10

Adults (18-64 years)	897
From 65 to 84 years	54
85 years and over	4

Subject disposition

Recruitment

Recruitment details:

Participants were recruited from 16 study centers located in China

Pre-assignment

Screening details:

Of the 985 subjects who signed an informed consent for this study, 3 subjects were exited as screen failures. This reporting group includes all enrolled and randomized subjects (982).

Period 1

Period 1 title	Overall (overall period)
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Single blind
Roles blinded	Assessor ^[1]

Arms

Are arms mutually exclusive?	Yes
Arm title	Moxifloxacin

Arm description:

Moxifloxacin ophthalmic solution, 0.5%, 1 drop instilled 3 times per day (TID) in each eye for 7 days with a test-of-cure (TOC) at Day 9

Arm type	Experimental
Investigational medicinal product name	Moxifloxacin ophthalmic solution, 0.5%
Investigational medicinal product code	
Other name	VIGAMOX®
Pharmaceutical forms	Eye drops, solution
Routes of administration	Ophthalmic use

Dosage and administration details:

1 drop instilled 3 times per day (TID) in each eye for 7 days

Arm title	Ofloxacin
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Arm description:

Ofloxacin ophthalmic solution, 0.3%, 1 drop instilled 3 times per day (TID) in each eye for 7 days with a test-of-cure (TOC) at Day 9

Arm type	Active comparator
Investigational medicinal product name	Ofloxacin ophthalmic solution, 0.3%
Investigational medicinal product code	
Other name	Tarivid® Eye Drops
Pharmaceutical forms	Eye drops, solution
Routes of administration	Ophthalmic use

Dosage and administration details:

1 drop instilled 3 times per day (TID) in each eye for 7 days

Notes:

[1] - The roles blinded appear inconsistent with a simple blinded trial.

Justification: This was a single-blind trial and only the Assessor was masked.

Number of subjects in period 1	Moxifloxacin	Ofloxacin
Started	489	493
Completed	469	476
Not completed	20	17
Adverse event, non-fatal	4	4
Withdrawal by Subject	-	1
Protocol Violation	3	-
Patient decision unrelated to Advs Event	11	11
Lost to follow-up	2	1

Baseline characteristics

Reporting groups

Reporting group title	Moxifloxacin
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Reporting group description:

Moxifloxacin ophthalmic solution, 0.5%, 1 drop instilled 3 times per day (TID) in each eye for 7 days with a test-of-cure (TOC) at Day 9

Reporting group title	Ofloxacin
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Reporting group description:

Ofloxacin ophthalmic solution, 0.3%, 1 drop instilled 3 times per day (TID) in each eye for 7 days with a test-of-cure (TOC) at Day 9

Reporting group values	Moxifloxacin	Ofloxacin	Total
Number of subjects	489	493	982
Age categorical			
Units: Subjects			

Age continuous			
This analysis population includes all participants who were administered study medication or potentially used study medication.			
Units: years			
arithmetic mean	37.4	38.4	
standard deviation	± 15.54	± 15.83	-
Gender categorical			
This analysis population includes all participants who were administered study medication or potentially used study medication.			
Units: Subjects			
Female	254	265	519
Male	235	228	463

End points

End points reporting groups

Reporting group title	Moxifloxacin
Reporting group description: Moxifloxacin ophthalmic solution, 0.5%, 1 drop instilled 3 times per day (TID) in each eye for 7 days with a test-of-cure (TOC) at Day 9	
Reporting group title	Ofloxacin
Reporting group description: Ofloxacin ophthalmic solution, 0.3%, 1 drop instilled 3 times per day (TID) in each eye for 7 days with a test-of-cure (TOC) at Day 9	

Primary: Clinical Cure Rate

End point title	Clinical Cure Rate
End point description: Ocular signs of bacterial conjunctivitis (bulbar conjunctival injection and conjunctival discharge/exudates) were rated by the investigator on a 4-point scale, with 0=normal/absent; 1=mild; 2=moderate, and 3=severe. Clinical cure rate is presented as the percentage of participants for which the sum of the numerical scores for the 2 cardinal ocular signs of bacterial conjunctivitis was 0 at Day 9 TOC/Exit Visit. This analysis population includes all patients who received study medication, had no major protocol deviations, had bacteria present at Day 1 visit, and had baseline and TOC/exit data or early exit data.	
End point type	Primary
End point timeframe: Day 9	

End point values	Moxifloxacin	Ofloxacin		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	295	291		
Units: percentage of participants				
number (not applicable)	85.4	81.4		

Statistical analyses

Statistical analysis title	Clinical Cure Rate
Comparison groups	Moxifloxacin v Ofloxacin
Number of subjects included in analysis	586
Analysis specification	Pre-specified
Analysis type	non-inferiority
Parameter estimate	Mean difference (final values)
Point estimate	4

Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.8
upper limit	11.1

Primary: Microbiological Success Rate

End point title	Microbiological Success Rate
End point description:	
Microbiological specimen(s) from the affected eye(s) were collected according to a protocol-defined process. Microbiological success rate is presented as the percentage of participants for which the pre-therapy pathogens at Visit 1 (Day 1) were eradicated at Day 9 TOC/Exit Visit. This analysis population includes all patients who received study medication, had no major protocol deviations, had bacteria present at Day 1 visit, and had baseline and TOC/exit data or early exit data.	
End point type	Primary
End point timeframe:	
Day 9	

End point values	Moxifloxacin	Ofloxacin		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	295	291		
Units: percentage of participants				
number (not applicable)	95.3	94.8		

Statistical analyses

Statistical analysis title	Microbiological Success
Comparison groups	Moxifloxacin v Ofloxacin
Number of subjects included in analysis	586
Analysis specification	Pre-specified
Analysis type	non-inferiority
Parameter estimate	Mean difference (final values)
Point estimate	0.4
Confidence interval	
level	95 %
sides	2-sided
lower limit	-3.3
upper limit	7.7

Adverse events

Adverse events information^[1]

Timeframe for reporting adverse events:

Adverse events (AEs) were collected for the duration of the study (May 2012 to April 2014). This analysis group includes all patients who were administered or potentially used study medication.

Adverse event reporting additional description:

An adverse event was defined as any untoward medical occurrence in a patient who is administered a study treatment regardless of whether or not the event has a causal relationship with the treatment

Assessment type	Systematic
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Dictionary used

Dictionary name	MedDRA
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Dictionary version	15.0
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Reporting groups

Reporting group title	Moxifloxacin
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Reporting group description:

1 drop instilled TID in each eye for 7 days with a TOC at Day 9

Reporting group title	Ofloxacin
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Reporting group description:

1 drop instilled TID in each eye for 7 days with a TOC at Day 9

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.

Serious adverse events	Moxifloxacin	Ofloxacin	
Total subjects affected by serious adverse events			
subjects affected / exposed	1 / 489 (0.20%)	0 / 493 (0.00%)	
number of deaths (all causes)	0	0	
number of deaths resulting from adverse events	0	0	
Vascular disorders			
Hypertension			
subjects affected / exposed	1 / 489 (0.20%)	0 / 493 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

Frequency threshold for reporting non-serious adverse events: 5 %

Non-serious adverse events	Moxifloxacin	Ofloxacin	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	0 / 489 (0.00%)	0 / 493 (0.00%)	

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
12 August 2013	Added contents to the protocol in order to help better understand the efficacy of Moxifloxacin

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported