



Clinical trial results:

An Evaluation of the Safety and Efficacy of Moxifloxacin AF Ophthalmic Solution 0.5% for the Treatment of Bacterial Conjunctivitis in the USA Summary

EudraCT number	2017-002730-23
Trial protocol	Outside EU/EEA
Global end of trial date	17 May 2007

Results information

Result version number	v1 (current)
This version publication date	22 December 2017
First version publication date	22 December 2017

Trial information

Trial identification

Sponsor protocol code	C-04-38
-----------------------	---------

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT00331916
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Alcon Research, Ltd.
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	17 May 2007
Is this the analysis of the primary completion data?	Yes
Primary completion date	17 May 2007
Global end of trial reached?	Yes
Global end of trial date	17 May 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 safety and efficacy of Moxifloxacin AF Ophthalmic Solution 0.5% compared to Moxifloxacin AF Vehicle in the treatment of bacterial conjunctivitis in patients one month of age or older.

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	03 November 2005
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: 661
Worldwide total number of subjects	661
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)	113
Children (2-11 years)	241
Adolescents (12-17 years)	66

Adults (18-64 years)	226
From 65 to 84 years	14
85 years and over	1

Subject disposition

Recruitment

Recruitment details:

Subjects were recruited from 32 study centers located in the USA.

Pre-assignment

Screening details:

This reporting group includes all randomized and treated subjects (661).

Period 1

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

Arms

Are arms mutually exclusive?	Yes
Arm title	Moxifloxacin AF

Arm description:

Moxifloxacin AF Ophthalmic Solution, one drop into the conjunctival sac of both eyes two times a day for three days.

Arm type	Experimental
Investigational medicinal product name	Moxifloxacin Alternative Formulation (AF) Ophthalmic Solution 0.5%
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Eye drops, solution
Routes of administration	Ophthalmic use , Ocular use, Topical use

Dosage and administration details:

One drop into the conjunctival sac of both eyes two times a day for three days. The total assessment period was 7 days.

Arm title	Moxifloxacin AF Vehicle
------------------	-------------------------

Arm description:

Moxifloxacin AF Vehicle, one drop into the conjunctival sac of both eyes two times a day for three days.

Arm type	Active comparator
Investigational medicinal product name	Moxifloxacin Alternative Formulation (AF) Vehicle
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Eye drops, solution
Routes of administration	Ocular use, Ophthalmic use , Topical use

Dosage and administration details:

One drop into the conjunctival sac of both eyes two times a day for three days. The total assessment period was 7 days.

Number of subjects in period 1	Moxifloxacin AF	Moxifloxacin AF Vehicle
Started	331	330
Completed	309	270
Not completed	22	60
Adverse event, non-fatal	5	5
Treatment Failure	7	32
Other	1	4
Decision Unrelated to an Adverse Event	5	5
Lost to follow-up	3	6
Noncompliance	1	8

Baseline characteristics

Reporting groups

Reporting group title	Moxifloxacin AF
Reporting group description: Moxifloxacin AF Ophthalmic Solution, one drop into the conjunctival sac of both eyes two times a day for three days.	
Reporting group title	Moxifloxacin AF Vehicle
Reporting group description: Moxifloxacin AF Vehicle, one drop into the conjunctival sac of both eyes two times a day for three days.	

Reporting group values	Moxifloxacin AF	Moxifloxacin AF Vehicle	Total
Number of subjects	331	330	661
Age categorical Units: Subjects			
Infants and toddlers (28 days-23 months)	62	51	113
Children (2-11 years)	117	124	241
Adolescents (12-17 years)	31	35	66
Adults (18-64 years)	114	112	226
From 65-84 years	7	7	14
85 years and over	0	1	1
Gender categorical Units: Subjects			
Female	184	189	373
Male	147	141	288

End points

End points reporting groups

Reporting group title	Moxifloxacin AF
Reporting group description: Moxifloxacin AF Ophthalmic Solution, one drop into the conjunctival sac of both eyes two times a day for three days.	
Reporting group title	Moxifloxacin AF Vehicle
Reporting group description: Moxifloxacin AF Vehicle, one drop into the conjunctival sac of both eyes two times a day for three days.	

Primary: Clinical cure rate at the Day 7 Exit/Test-of-cure (TOC) Visit

End point title	Clinical cure rate at the Day 7 Exit/Test-of-cure (TOC) Visit
End point description: Clinical cure was attained when the sum of the two cardinal ocular signs of bacterial infections (bulbar conjunctival injection and conjunctival discharge/exudate) was zero (ie, normal or absent). Only one eye (study eye) contributed to the analysis. This analysis population includes all subjects who received drug, had at least one on-therapy visit, met pre-randomization inclusion and exclusion criteria and were pathogen positive for bacteria on Day 1 (Modified Intent-to-Treat (MITT) Analysis Set).	
End point type	Primary
End point timeframe: Day 7	

End point values	Moxifloxacin AF	Moxifloxacin AF Vehicle		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	177	165		
Units: Percentage				
number (not applicable)	72.3	67.3		

Statistical analyses

Statistical analysis title	Clinical Cure at Day 7
Comparison groups	Moxifloxacin AF v Moxifloxacin AF Vehicle
Number of subjects included in analysis	342
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.3097
Method	Chi-squared

Primary: Microbiological success rate at the Day 7 Exit/TOC Visit

End point title	Microbiological success rate at the Day 7 Exit/TOC Visit
-----------------	--

End point description:

Microbiological success was defined as the eradication of pre-therapy pathogens. Only one eye (study eye) contributed to the analysis. MITT Analysis Set.

End point type	Primary
----------------	---------

End point timeframe:

Day 7

End point values	Moxifloxacin AF	Moxifloxacin AF Vehicle		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	177	165		
Units: Percentage				
number (not applicable)	84.2	66.1		

Statistical analyses

Statistical analysis title	Microbiological success rate at Day 7
Comparison groups	Moxifloxacin AF v Moxifloxacin AF Vehicle
Number of subjects included in analysis	342
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.0001
Method	Chi-squared

Adverse events

Adverse events information^[1]

Timeframe for reporting adverse events:

Adverse events 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.

Assessment type	Systematic
-----------------	------------

Dictionary used

Dictionary name	MedDRA
Dictionary version	8.0

Reporting groups

Reporting group title	Moxifloxacin AF
-----------------------	-----------------

Reporting group description:

Moxifloxacin AF Ophthalmic Solution, one drop into the conjunctival sac of both eyes two times a day for three days.

Reporting group title	Moxifloxacin AF Vehicle
-----------------------	-------------------------

Reporting group description:

Moxifloxacin AF Vehicle, one drop into the conjunctival sac of both eyes two times a day for three days.

Serious adverse events	Moxifloxacin AF	Moxifloxacin AF Vehicle	
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 331 (0.00%)	0 / 330 (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 %

Non-serious adverse events	Moxifloxacin AF	Moxifloxacin AF Vehicle	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	0 / 331 (0.00%)	0 / 330 (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

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported