Clinical trial results:
Moxifloxacin AF Ophthalmic Solution for Treatment of Bacterial Conjunctivitis

Summary

EudraCT number	2017-002729-39
Trial protocol	Outside EU/EEA
Global end of trial date	02 March 2010

Results information

Result version number	v1 (current)
This version publication date	21 December 2017
First version publication date	21 December 2017

Trial information

Trial identification

Sponsor protocol code	C-07-40

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT00759148
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 0127666733391, dennis.wong@novartis.com
Scientific contact	Ophthalmology Unit, Novartis Pharmaceuticals, +44 0127666733391, 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	02 March 2010
Is this the analysis of the primary completion data?	Yes
Primary completion date	02 March 2010
Global end of trial reached?	Yes
Global end of trial date	02 March 2010
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	13 October 2008
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: 1179
Worldwide total number of subjects	1179
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)	96
Children (2-11 years)	358
Adolescents (12-17 years)	143

Adults (18-64 years)	487
From 65 to 84 years	86
85 years and over	9

Subject disposition

Recruitment

Recruitment details:

Subjects were recruited from 108 study centers located in the USA.

Pre-assignment

Screening details:

1179 subjects with bacterial conjunctivitis were randomized and treated with Moxifloxacin AF or Moxifloxacin AF vehicle

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, Carer, Assessor

Arms

Are arms mutually exclusive?	Yes
Arm title	Moxifloxacin AF

Arm description:

Moxifloxacin AF Ophthalmic Solution

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

Dosage and administration details:

1 drop in each eye, twice daily for 3 days

Arm title	Moxifloxacin AF Vehicle

Arm description:

Moxifloxacin AF Ophthalmic Solution Vehicle

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

Dosage and administration details:

1 drop in each eye, twice daily for 3 days

Number of subjects in period 1	Moxifloxacin AF	Moxifloxacin AF Vehicle
Started	593	586
Completed	579	554
Not completed	14	32
Adverse event, non-fatal	1	6
Treatment Failure	6	10
Other	1	-
Patient's Decision Unrelated to an Adverse Event	3	7
Lost to follow-up	3	9

Baseline characteristics

Reporting groups	
Reporting group title	Moxifloxacin AF
Reporting group description: Moxifloxacin AF Ophthalmic Solution	
Reporting group title	Moxifloxacin AF Vehicle
Reporting group description: Moxifloxacin AF Ophthalmic Solution Vehicle	

Reporting group values	Moxifloxacin AF	Moxifloxacin AF Vehicle	Total
Number of subjects	593	586	1179
Age categorical Units: Subjects			
Infants and toddlers (28 days-23 months)	49	47	96
Children (2-11 years)	174	184	358
Adolescents (12-17 years)	71	72	143
Adults (18-64 years)	257	230	487
From 65-84 years	38	48	86
85 years and over	4	5	9
Gender categorical Units: Subjects			
Female	353	338	691
Male	240	248	488

End points

End points reporting groups	
Reporting group title	Moxifloxacin AF
Reporting group description: Moxifloxacin AF Ophthalmic Solution	
Reporting group title	Moxifloxacin AF Vehicle
Reporting group description: Moxifloxacin AF Ophthalmic Solution Vehicle	

Primary: Clinical cure at the Day 4 (EOT)/Exit Visit	
End point title	Clinical cure at the Day 4 (EOT)/Exit Visit
End point description: Clinical cure was attained if the sum of the 2 cardinal ocular signs of bacterial conjunctivitis (bulbar conjunctival injection and conjunctival discharge/exudate) was zero (ie, normal or absent) 12-48 hours after the last dose. Only one eye (study eye) contributed to the analysis. This analysis population includes all patients who received drug, had at least 1 on-therapy visit and were pathogen positive for bacteria on Day 1 (Microbiological Intent-to-Treat (MBITT) Analysis Set).	
End point type	Primary
End point timeframe: Day 4	

End point values	Moxifloxacin AF	Moxifloxacin AF Vehicle		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	424	423		
Units: Percentage of subjects				
number (not applicable)	62.5	50.6		

Statistical analyses

Statistical analysis title	Clinical Cure at the Day 4 (EOT)/Exit Visit
Comparison groups	Moxifloxacin AF v Moxifloxacin AF Vehicle
Number of subjects included in analysis	847
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.0005
Method	Chi-squared

Secondary: Microbiological success at the Day 4 (EOT)/Exit Visit	
End point title	Microbiological success at the Day 4 (EOT)/Exit Visit

End point description:

Microbiological success was attained if the pre-therapy bacterial pathogens were eradicated 12-48 hours after the last dose. Only one eye (study eye) contributed to the analysis. MBITT Analysis Set.

End point type	Secondary

End point timeframe:

Day 4

End point values	Moxifloxacin AF	Moxifloxacin AF Vehicle		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	424	423		
Units: Percentage of subjects				
number (not applicable)	74.5	56		

Statistical analyses

No statistical analyses for this end point

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	11.0

Reporting groups

Reporting group title	Moxifloxacin AF Vehicle
Reporting group description: -	
Reporting group title	Moxifloxacin AF

Reporting group description: -

Serious adverse events	Moxifloxacin AF Vehicle	Moxifloxacin AF	
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 586 (0.00%)	0 / 593 (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 Vehicle	Moxifloxacin AF	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	0 / 586 (0.00%)	0 / 593 (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