# 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<br>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<br>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