



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