



Clinical trial results:

A Comparative Study of Olopatadine Hydrochloride Ophthalmic Solution 0.2% QD vs Olopatadine Hydrochloride Ophthalmic Solution 0.1% BID in the Treatment of Allergic Conjunctivitis in Chinese Subjects

Summary

| | |
|--------------------------|-----------------|
| EudraCT number | 2016-004317-27 |
| Trial protocol | Outside EU/EEA |
| Global end of trial date | 15 October 2015 |

Results information

| | |
|--------------------------------|-------------------|
| Result version number | v1 (current) |
| This version publication date | 15 September 2017 |
| First version publication date | 15 September 2017 |

Trial information

Trial identification

| | |
|-----------------------|----------|
| Sponsor protocol code | C-12-010 |
|-----------------------|----------|

Additional study identifiers

| | |
|------------------------------------|-------------|
| ISRCTN number | - |
| ClinicalTrials.gov id (NCT number) | NCT02322216 |
| WHO universal trial number (UTN) | - |

Notes:

Sponsors

| | |
|------------------------------|--|
| Sponsor organisation name | Novartis Pharmaceuticals |
| Sponsor organisation address | Park View, Riverside way, Watchmoor Park, Camberley , Surrey, United Kingdom, GU15 3YL |
| Public contact | Dennis Wong, Novartis Pharmaceuticals, dennis.wong@novartis.com |
| Scientific contact | Dennis Wong, Novartis Pharmaceuticals, 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 October 2015 |
| Is this the analysis of the primary completion data? | Yes |
| Primary completion date | 15 October 2015 |
| Global end of trial reached? | Yes |
| Global end of trial date | 15 October 2015 |
| 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 olopatadine 0.2% QD (once per day) compared to olopatadine 0.1% BID (twice per day) in the treatment of ocular itching associated with allergic conjunctivitis.

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 | 30 December 2014 |
| 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 | China: 252 |
| Worldwide total number of subjects | 252 |
| 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) | 11 |

| | |
|----------------------|-----|
| Adults (18-64 years) | 218 |
| From 65 to 84 years | 6 |
| 85 years and over | 0 |

Subject disposition

Recruitment

Recruitment details:

Participants were recruited from 10 study centers located in China.

Pre-assignment

Screening details:

Of the 383 subjects who signed an informed consent form, 130 were exited as screen failures prior to randomization and 253 were randomized. This reporting group includes all randomized and treated subjects (252).

Period 1

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

Arms

| | |
|------------------------------|---------|
| Are arms mutually exclusive? | Yes |
| Arm title | PATADAY |

Arm description:

Olopatadine hydrochloride ophthalmic solution 0.2% in the morning and olopatadine 0.2% Vehicle in the evening, 1 drop in each eye for 14 days

| | |
|--|--|
| Arm type | Experimental |
| Investigational medicinal product name | Olopatadine Hydrochloride Ophthalmic Solution 0.2% |
| Investigational medicinal product code | EXZ829B |
| Other name | PATADAY® |
| Pharmaceutical forms | Eye drops, solution |
| Routes of administration | Ocular use |

Dosage and administration details:

Olopatadine hydrochloride ophthalmic solution 0.2% in the morning, 1 drop in each eye for 14 days

| | |
|--|---------------------|
| Investigational medicinal product name | Placebo |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Eye drops, solution |
| Routes of administration | Ocular use |

Dosage and administration details:

Olopatadine 0.2% vehicle in the evening, 1 drop in each eye for 14 days

| | |
|------------------|---------|
| Arm title | PATANOL |
|------------------|---------|

Arm description:

Olopatadine hydrochloride ophthalmic solution 0.1%, 1 drop in each eye in the morning and evening, for 14 days

| | |
|--|--|
| Arm type | Active comparator |
| Investigational medicinal product name | Olopatadine Hydrochloride Ophthalmic Solution 0.1% |
| Investigational medicinal product code | |
| Other name | PATANOL® |
| Pharmaceutical forms | Eye drops, solution |
| Routes of administration | Ocular use |

Dosage and administration details:

Olopatadine hydrochloride ophthalmic solution 0.1%, 1 drop in each eye in the morning and evening, for 14 days

Notes:

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

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

| Number of subjects in period 1 | PATADAY | PATANOL |
|---------------------------------------|---------|---------|
| Started | 126 | 126 |
| Completed | 124 | 123 |
| Not completed | 2 | 3 |
| Consent withdrawn by subject | 1 | 3 |
| Adverse event, non-fatal | 1 | - |

Baseline characteristics

Reporting groups

| | |
|-----------------------|---------|
| Reporting group title | PATADAY |
|-----------------------|---------|

Reporting group description:

Olopatadine hydrochloride ophthalmic solution 0.2% in the morning and olopatadine 0.2% Vehicle in the evening, 1 drop in each eye for 14 days

| | |
|-----------------------|---------|
| Reporting group title | PATANOL |
|-----------------------|---------|

Reporting group description:

Olopatadine hydrochloride ophthalmic solution 0.1%, 1 drop in each eye in the morning and evening, for 14 days

| Reporting group values | PATADAY | PATANOL | Total |
|---|---------|---------|-------|
| Number of subjects | 126 | 126 | 252 |
| Age categorical | | | |
| Units: Subjects | | | |
| 10-17 years | 14 | 14 | 28 |
| 18-64 years | 109 | 109 | 218 |
| ≥65 years | 3 | 3 | 6 |
| Gender categorical | | | |
| This analysis population includes all subjects who received study drug (Safety Analysis Set). | | | |
| Units: Subjects | | | |
| Female | 83 | 88 | 171 |
| Male | 43 | 38 | 81 |

End points

End points reporting groups

| | |
|---|---------|
| Reporting group title | PATADAY |
| Reporting group description: Olopatadine hydrochloride ophthalmic solution 0.2% in the morning and olopatadine 0.2% Vehicle in the evening, 1 drop in each eye for 14 days | |
| Reporting group title | PATANOL |
| Reporting group description: Olopatadine hydrochloride ophthalmic solution 0.1%, 1 drop in each eye in the morning and evening, for 14 days | |

Primary: Change From Baseline in Worst Ocular Itching Score During the 24 Hours Prior at Day 14

| | |
|---|--|
| End point title | Change From Baseline in Worst Ocular Itching Score During the 24 Hours Prior at Day 14 |
| End point description: Severity of ocular itching was evaluated as the worst score observed in the past 24 hours prior to each study visit. Ocular itching was assessed by the participant on a scale from 0-4, where 0=None and 4=Incapacitating itch. One eye (study eye) contributed to the analysis. This analysis population includes the Per Protocol Set with non-missing data. | |
| End point type | Primary |
| End point timeframe: Baseline, Day 14 | |

| End point values | PATADAY | PATANOL | | |
|----------------------------------|---------------------|----------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 118 | 112 | | |
| Units: Units on a scale | | | | |
| arithmetic mean (standard error) | -2.57 (\pm 0.09) | -2.62 (\pm 0.092) | | |

Statistical analyses

| | |
|--|--|
| Statistical analysis title | Change from baseline in mean itching score |
| Statistical analysis description: Treatment difference in mean itching score (worst itching score during 24 hours) change from baseline at Day 14 | |
| Comparison groups | PATADAY v PATANOL |

| | |
|---|--------------------------------|
| Number of subjects included in analysis | 230 |
| Analysis specification | Pre-specified |
| Analysis type | non-inferiority |
| Parameter estimate | Mean difference (final values) |
| Point estimate | 0.05 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -0.17 |
| upper limit | 0.26 |

Adverse events

Adverse events information^[1]

Timeframe for reporting adverse events:

Adverse events (AEs) were collected from the time of informed consent and for the duration of participation in the study (2 weeks). This analysis group includes all participants who received study treatment.

Adverse event reporting additional description:

An AE is defined as any untoward medical occurrence in a subject who is administered a study treatment regardless of whether or not the event has a causal relationship with the treatment. Reports of AEs were obtained through solicited and spontaneous comments from the participants.

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

Dictionary used

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|-----------------|--------|
| Dictionary name | MedDRA |
|-----------------|--------|

| | |
|--------------------|------|
| Dictionary version | 17.0 |
|--------------------|------|

Reporting groups

| | |
|-----------------------|---------|
| Reporting group title | PATADAY |
|-----------------------|---------|

Reporting group description:

All subjects treated with olopatadine hydrochloride ophthalmic solution 0.2%

| | |
|-----------------------|---------|
| Reporting group title | PATANOL |
|-----------------------|---------|

Reporting group description:

All subjects treated with olopatadine hydrochloride ophthalmic solution 0.1%

| Serious adverse events | PATADAY | PATANOL | |
|---|-----------------|-----------------|--|
| Total subjects affected by serious adverse events | | | |
| subjects affected / exposed | 0 / 126 (0.00%) | 0 / 126 (0.00%) | |
| number of deaths (all causes) | 0 | 0 | |
| number of deaths resulting from adverse events | | | |

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

| Non-serious adverse events | PATADAY | PATANOL | |
|---|-----------------|-----------------|--|
| Total subjects affected by non-serious adverse events | | | |
| subjects affected / exposed | 0 / 126 (0.00%) | 0 / 126 (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