Clinical trial results:
Clinical Evaluation of 0.1% Olopatadine Hydrochloride Ophthalmic Solution in Pediatric Patients

Summary

EudraCT number	2017-003841-39
Trial protocol	Outside EU/EEA
Global end of trial date	04 July 2011

Results information

Result version number	v1 (current)
This version publication date	24 January 2018
First version publication date	24 January 2018

Trial information

Trial identification

Sponsor protocol code	JPN-P-2010-1

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT01109485
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Alcon Research, Japan
Sponsor organisation address	6201 S. Freeway, Fort Worth, Texas, 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	04 July 2011
Is this the analysis of the primary completion data?	Yes
Primary completion date	04 July 2011
Global end of trial reached?	Yes
Global end of trial date	04 July 2011
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 of Olopatadine Ophthalmic Solution 0.1% in Japanese children 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	27 February 2010
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	Japan: 70
Worldwide total number of subjects	70
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)	51
Adolescents (12-17 years)	19

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

Subject disposition

Recruitment

Recruitment details:

Subjects were recruited from 2 study centers located in Japan.

Pre-assignment

Screening details:

This reporting group includes all enrolled and randomized subjects (70).

Period 1

Period 1 title	Overall (overall period)
Is this the baseline period?	Yes
Allocation method	Not applicable
Blinding used	Not blinded

Arms

Arm title	Olopatadine

Arm description:

Olopatadine hydrochloride ophthalmic solution 0.1%, 1-2 drops q.i.d. (4 times per day:, morning, afternoon, evening, and at bedtime) for 4 weeks

Arm type	Experimental
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	Ophthalmic use

Dosage and administration details:

Olopatadine hydrochloride ophthalmic solution 0.1%, 1-2 drops QID (morning, afternoon, evening, and at bedtime) for 4 weeks

Number of subjects in period 1	Olopatadine
Started	70
Completed	42
Not completed	28
Reason not given	27
Protocol deviation	1

Baseline characteristics

Reporting groups	
Reporting group title	Olopatadine
Reporting group description:	
Olopatadine hydrochloride ophthalmic solution 0.1%, 1-2 drops q.i.d. (4 times per day:, morning, afternoon, evening, and at bedtime) for 4 weeks	

Reporting group values	Olopatadine	Total	
Number of subjects	70	70	
Age categorical Units: Subjects			
Children (2-11 years)	51	51	
Adolescents (12-17 years)	19	19	
Gender categorical Units: Subjects			
Female	37	37	
Male	33	33	

End points

End points reporting groups

Reporting group title	Olopatadine
Reporting group description:	
Olopatadine hydrochloride ophthalmic solution 0.1%, 1-2 drops q.i.d. (4 times per day:, morning, afternoon, evening, and at bedtime) for 4 weeks	
Subject analysis set title	Baseline
Subject analysis set type	Sub-group analysis
Subject analysis set description:	
Efficacy Analysis Set at Baseline	
Subject analysis set title	Week 1
Subject analysis set type	Sub-group analysis
Subject analysis set description:	
Efficacy Analysis Set at Week 1	
Subject analysis set title	Week 2
Subject analysis set type	Sub-group analysis
Subject analysis set description:	
Efficacy Analysis Set at Week 2	
Subject analysis set title	Week 4
Subject analysis set type	Sub-group analysis
Subject analysis set description:	
Efficacy Analysis Set at Week 4	

Primary: Number of Adverse Drug Reactions (ADR)

End point title	Number of Adverse Drug Reactions (ADR)[1]
End point description:	
An adverse event (AE) is defined as any unfavorable and unintended sign, symptom, or disease temporally associated with the use of an investigational product (IP), whether or not considered related to the investigational product. Of the AEs reported, all cases judged as having a possible causal relationship to the investigational product (IP) qualified as ADRs. This analysis population includes all subjects exposed to IP (Safety Analysis Set).	
End point type	Primary
End point timeframe:	
Up through Week 4	

Notes:

[1] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: No formal statistical analysis was planned or conducted for this primary endpoint.

End point values	Olopatadine			
Subject group type	Reporting group			
Number of subjects analysed	70			
Units: number	0			

Statistical analyses

No statistical analyses for this end point

Primary: Severity Score of Subjective Symptoms by Visit

End point title	Severity Score of Subjective Symptoms by Visit[2]

End point description:

The severity score of subjective symptoms (eye pruritus, foreign body sensation in eyes, eye pain, lacrimation, photophobia, and eye discharge) was assessed by interviewing subjects at scheduled visits. Each symptom was rated on a scale of 0-3, where 0=None, 1=Mild, 2=Moderate, and 3=Severe. This analysis population includes all treated subjects with a follow-up period of four weeks (Efficacy Analysis Set).

End point type	Primary

End point timeframe:

Baseline, Week 1, Week 2, Week 4

Notes:

[2] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: This was a one-arm descriptive study; no hypothesis testing was performed. Descriptive statistics were provided.

End point values	Baseline	Week 1	Week 2	Week 4
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	42[3]	38[4]	26[5]	41[6]
Units: units on a scale				
arithmetic mean (standard deviation)				
Eye Pruritus	1.64 (± 0.94)	1.04 (± 0.9)	0.9 (± 0.87)	0.7 (± 0.9)
Eye Discharge	0.61 (± 0.64)	0.25 (± 0.52)	0.35 (± 0.71)	0.17 (± 0.54)
Lacrimation	0.52 (± 0.74)	0.34 (± 0.66)	0.15 (± 0.42)	0.11 (± 0.39)
Photophobia	0.32 (± 0.72)	0.16 (± 0.44)	0.17 (± 0.47)	0.2 (± 0.46)
Foreign Body Sensation in Eyes	0.33 (± 0.61)	0.24 (± 0.54)	0.21 (± 0.46)	0.22 (± 0.57)
Eye Pain	0.35 (± 0.62)	0.2 (± 0.5)	0.17 (± 0.47)	0.13 (± 0.44)

Notes:

[3] - Efficacy Analysis Set, n=42, 42, 42, 41, 42, 41

[4] - Efficacy Analysis Set, n=38, 38, 38, 37, 38, 37

[5] - Efficacy Analysis Set

[6] - Efficacy Analysis Set, n=41, 41, 41, 42, 41, 41

Statistical analyses

No statistical analyses for this end point

Primary: Severity Score of Objective Symptoms by Visit

End point title	Severity Score of Objective Symptoms by Visit[7]

End point description:

The severity score of objective symptoms (conjunctival hyperaemia, conjunctival swelling, conjunctival follicles, conjunctival papillae, conjunctival oedema and corneal complications) was assessed by interviewing subjects at scheduled visits. Each symptom was rated on a scale of 0-3, where 0=None, 1=Mild, 2=Moderate, and 3=Severe. Efficacy Analysis Set.

End point type	Primary

End point timeframe:

Baseline, Week 1, Week 2, Week 4

Notes:

[7] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: This was a one-arm descriptive study; no hypothesis testing was performed. Descriptive statistics were provided.

End point values	Baseline	Week 1	Week 2	Week 4
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	42[8]	38[9]	26[10]	42[11]
Units: units on a scale				
arithmetic mean (standard deviation)				
Palpebral Conjunctiva: Hyperaemia	1.43 (± 0.61)	0.72 (± 0.65)	0.71 (± 0.46)	0.67 (± 0.67)
Palpebral Conjunctiva: Swelling	1.18 (± 0.73)	0.47 (± 0.62)	0.44 (± 0.57)	0.27 (± 0.5)
Palpebral Conjunctiva: Follicle	0.65 (± 0.61)	0.41 (± 0.62)	0.37 (± 0.53)	0.26 (± 0.52)
Palpebral Conjunctiva: Papillae	1.6 (± 0.73)	1.04 (± 0.62)	0.94 (± 0.7)	0.73 (± 0.68)
Palpebral Conjunctiva: Giant Papillae	0.21 (± 0.52)	0.01 (± 0.12)	0.12 (± 0.51)	0.06 (± 0.28)
Bulbar Conjunctiva: Hyperaemia	0.83 (± 0.71)	0.32 (± 0.55)	0.35 (± 0.56)	0.26 (± 0.49)
Bulbar Conjunctiva: Oedema	0.6 (± 0.71)	0.21 (± 0.5)	0.15 (± 0.46)	0.13 (± 0.4)
Limbus: Trantas' Dots	0.1 (± 0.4)	0.07 (± 0.3)	0.12 (± 0.58)	0.05 (± 0.31)
Limbus: Swelling	0.07 (± 0.26)	0.04 (± 0.2)	0.12 (± 0.58)	0.05 (± 0.31)
Cornea: Epithelium Disorder	0.05 (± 0.21)	0.03 (± 0.16)	0.08 (± 0.27)	0.02 (± 0.15)

Notes:

[8] - Efficacy Analysis Set

[9] - Efficacy Analysis Set, n=38, 38, 38, 38, 38, 38, 38, 38, 38, 36

[10] - Efficacy Analysis Set

[11] - Efficacy Analysis Set

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	13.0

Reporting groups

Reporting group title	Olopatadine

Reporting group description:

Olopatadine hydrochloride ophthalmic solution 0.1%, 1-2 drops q.i.d. (4 times per day:, morning, afternoon, evening, and at bedtime) for 4 weeks

Serious adverse events	Olopatadine		
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 70 (0.00%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events	0		

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

Non-serious adverse events	Olopatadine		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	0 / 70 (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 were reported in this study.

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