



Clinical trial results:

An Evaluation of Moxidex Ophthalmic Solution for Treatment of Marginal Corneal Infiltrates

Summary

EudraCT number	2017-002732-17
Trial protocol	Outside EU/EEA
Global end of trial date	09 February 2009

Results information

Result version number	v1 (current)
This version publication date	04 January 2018
First version publication date	04 January 2018

Trial information

Trial identification

Sponsor protocol code	C-05-04
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Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT00579020
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Alcon Research Ltd
Sponsor organisation address	6201 S. Freeway, Fort Worth, Texas, 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	09 February 2009
Is this the analysis of the primary completion data?	Yes
Primary completion date	09 February 2009
Global end of trial reached?	Yes
Global end of trial date	09 February 2009
Was the trial ended prematurely?	Yes

Notes:

General information about the trial

Main objective of the trial:

The purpose of this study was to evaluate the efficacy and safety of Moxidex Ophthalmic Solution for the treatment of marginal corneal infiltrates.

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	10 December 2007
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: 144
Worldwide total number of subjects	144
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)	0
Adolescents (12-17 years)	14

Adults (18-64 years)	118
From 65 to 84 years	11
85 years and over	1

Subject disposition

Recruitment

Recruitment details:

Subjects were recruited from 26 study centers located in US.

Pre-assignment

Screening details:

This reporting group includes all enrolled and randomized subjects (144).

Period 1

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

Arms

Are arms mutually exclusive?	Yes
Arm title	Moxidex

Arm description:

Moxidex Ophthalmic Solution, administered in the affected eye 4 times daily; 1 drop in cul-de-sac, 4 drops on closed lids for 7 days.

Arm type	Experimental
Investigational medicinal product name	Moxifloxacin Ophthalmic Solution 0.5%/dexamethasone phosphate 0.1%
Investigational medicinal product code	FID 107535
Other name	Moxidex
Pharmaceutical forms	Eye drops, solution
Routes of administration	Topical use , Ocular use

Dosage and administration details:

Dosed in the affected eye 4 times daily; 1 drop in cul-de-sac, 4 drops on closed lids

Arm title	Moxifloxacin
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Arm description:

Moxifloxacin Ophthalmic Solution 0.5%, administered in the affected eye 4 times daily; 1 drop in cul-de-sac, 4 drops on closed lids for 7 days.

Arm type	Reference Comparator
Investigational medicinal product name	Moxifloxacin Ophthalmic Solution 0.5%
Investigational medicinal product code	FID 106489
Other name	Moxifloxacin
Pharmaceutical forms	Eye drops, solution
Routes of administration	Ocular use, Topical use

Dosage and administration details:

Dosed in the affected eye 4 times daily; 1 drop in cul-de-sac, 4 drops on closed lids

Arm title	Dexamethasone
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Arm description:

Dexamethasone Phosphate Solution 0.1%, administered in the affected eye 4 times daily; 1 drop in cul-de-sac, 4 drops on closed lids for 7 days.

Arm type	Reference Comparator
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Investigational medicinal product name	Dexamethasone Phosphate Solution 0.1%
Investigational medicinal product code	FID 107595
Other name	
Pharmaceutical forms	Eye drops, solution
Routes of administration	Ocular use, Topical use
Dosage and administration details:	
Dosed in the affected eye 4 times daily; 1 drop in cul-de-sac, 4 drops on closed lids	

Notes:

[1] - The roles blinded appear to be inconsistent with a double blind trial.

Justification: In this study, treatments were double-masked, unknown to the subject and the clinical assessor.

Number of subjects in period 1	Moxidex	Moxifloxacin	Dexamethasone
Started	50	46	48
Completed	48	40	43
Not completed	2	6	5
Adverse event, non-fatal	-	-	1
Treatment Failure	-	3	1
Other	-	1	-
Patient's Decision Unrelated to an Adverse Event	1	2	1
Lost to follow-up	1	-	2

Baseline characteristics

Reporting groups

Reporting group title	Moxidex
Reporting group description: Moxidex Ophthalmic Solution, administered in the affected eye 4 times daily; 1 drop in cul-de-sac, 4 drops on closed lids for 7 days.	
Reporting group title	Moxifloxacin
Reporting group description: Moxifloxacin Ophthalmic Solution 0.5%, administered in the affected eye 4 times daily; 1 drop in cul-de-sac, 4 drops on closed lids for 7 days.	
Reporting group title	Dexamethasone
Reporting group description: Dexamethasone Phosphate Solution 0.1%, administered in the affected eye 4 times daily; 1 drop in cul-de-sac, 4 drops on closed lids for 7 days.	

Reporting group values	Moxidex	Moxifloxacin	Dexamethasone
Number of subjects	50	46	48
Age categorical Units: Subjects			
Adolescents (12-17 years)	2	6	6
Adults (18-64 years)	44	37	37
≥ 65 Years	4	3	5
Gender categorical Units: Subjects			
Female	28	31	36
Male	22	15	12

Reporting group values	Total		
Number of subjects	144		
Age categorical Units: Subjects			
Adolescents (12-17 years)	14		
Adults (18-64 years)	118		
≥ 65 Years	12		
Gender categorical Units: Subjects			
Female	95		
Male	49		

End points

End points reporting groups

Reporting group title	Moxidex
Reporting group description: Moxidex Ophthalmic Solution, administered in the affected eye 4 times daily; 1 drop in cul-de-sac, 4 drops on closed lids for 7 days.	
Reporting group title	Moxifloxacin
Reporting group description: Moxifloxacin Ophthalmic Solution 0.5%, administered in the affected eye 4 times daily; 1 drop in cul-de-sac, 4 drops on closed lids for 7 days.	
Reporting group title	Dexamethasone
Reporting group description: Dexamethasone Phosphate Solution 0.1%, administered in the affected eye 4 times daily; 1 drop in cul-de-sac, 4 drops on closed lids for 7 days.	

Primary: Resolution of Corneal Stromal Infiltrates at Day 10 (Test of Cure [TOC])

End point title	Resolution of Corneal Stromal Infiltrates at Day 10 (Test of Cure [TOC])[¹]
End point description: Resolution (complete clearing) of corneal stromal infiltrate(s)) was defined by its absence in the study eye at Day 10, regardless of the presence of scarring or haze. Reported as a percentage of total subjects with resolution.	
End point type	Primary
End point timeframe: Day 10 (TOC)	

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: Due to cancellation of the study, no inferential statistical analyses were performed.

Descriptive statistics only were presented for the primary efficacy variable.

End point values	Moxidex	Moxifloxacin	Dexamethasone	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	47 ^[2]	43 ^[3]	44 ^[4]	
Units: Percentage of subjects				
number (not applicable)	91.5	79.1	90.9	

Notes:

[2] - All subjects who received treatment (Safety Analysis Set) with non-missing data at TOC

[3] - Safety Analysis Set with non-missing data at TOC

[4] - Safety Analysis Set with non-missing data at TOC

Statistical analyses

No statistical analyses for this end point

Secondary: Microbiological Success at Day 10 (TOC)

End point title	Microbiological Success at Day 10 (TOC)
End point description: Microbiological success was defined as eradication of all pre-therapy bacteria from the lid of the study eye at the Day 10 (TOC) visit. Reported as a percentage of total subjects with success. This analysis	

population, a culture positive subset of the safety analysis set, includes all subjects who were culture positive (ie, any bacteria recovered) in the study eye at baseline.

End point type	Secondary
End point timeframe:	
Day 10 (TOC)	

End point values	Moxidex	Moxifloxacin	Dexamethasone	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	20 ^[5]	17 ^[6]	15 ^[7]	
Units: Percentage of subjects				
number (not applicable)	85	94.1	80	

Notes:

[5] - All subjects who were culture positive (ie, any bacteria recovered) in the study eye at baseline.

[6] - All subjects who were culture positive (ie, any bacteria recovered) in the study eye at baseline.

[7] - All subjects who were culture positive (ie, any bacteria recovered) in the study eye at baseline.

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

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.

Adverse event reporting additional description:

Only total subjects affected by non-serious AEs that occur at >5% are reported.

Assessment type	Systematic
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Dictionary used

Dictionary name	MedDRA
Dictionary version	11.0

Reporting groups

Reporting group title	Moxidex
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Reporting group description: -

Reporting group title	Moxifloxacin
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Reporting group description: -

Reporting group title	Dexamethasone
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Reporting group description: -

Serious adverse events	Moxidex	Moxifloxacin	Dexamethasone
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 50 (0.00%)	0 / 46 (0.00%)	0 / 48 (0.00%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events			

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

Non-serious adverse events	Moxidex	Moxifloxacin	Dexamethasone
Total subjects affected by non-serious adverse events			
subjects affected / exposed	0 / 50 (0.00%)	3 / 46 (6.52%)	0 / 48 (0.00%)
Eye disorders			
Corneal Infiltrates			
subjects affected / exposed	0 / 50 (0.00%)	3 / 46 (6.52%)	0 / 48 (0.00%)
occurrences (all)	0	4	0

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
05 November 2007	To change the primary efficacy variable based on recommendation from Health Authority

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

Limitations of the trial such as small numbers of subjects analysed or technical problems leading to unreliable data.

Study was terminated due to lack of sufficient efficacy and not related to safety. Subjects currently enrolled at the time of termination were allowed to complete their remaining study visits.

Notes: