



Clinical trial results:

Multi-centre, randomised, double blind, placebo-controlled, parallel, phase III study to assess the safety, tolerability and efficacy of Bilastine ophthalmic solution 0.6% in children

Summary

EudraCT number	2020-002098-86
Trial protocol	ES
Global end of trial date	30 November 2022

Results information

Result version number	v1 (current)
This version publication date	05 April 2024
First version publication date	05 April 2024

Trial information

Trial identification

Sponsor protocol code	BOFT-0520/PED
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Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	-
WHO universal trial number (UTN)	-
Other trial identifiers	PIP number: EMEA-000347-PIP02-16

Notes:

Sponsors

Sponsor organisation name	FAES FARMA, S.A.
Sponsor organisation address	Avda. Autonomía, 10, Leioa (Bizkaia), Spain, 48940
Public contact	Inmaculada Gilaberte, FAES FARMA, S.A., 0034 944818300,
Scientific contact	Inmaculada Gilaberte, FAES FARMA, S.A., 0034 944818300,

Notes:

Paediatric regulatory details

Is trial part of an agreed paediatric investigation plan (PIP)	Yes
EMA paediatric investigation plan number(s)	EMA-000347-PIP02-16
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?	No

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	05 October 2023
Is this the analysis of the primary completion data?	No
Global end of trial reached?	Yes
Global end of trial date	30 November 2022
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To assess the safety of Bilastine ophthalmic solution 0.6% during long-term use in children

Protection of trial subjects:

This clinical trial was conducted in accordance with the protocol, the principles established in the current revised version of the Declaration of Helsinki on Ethical Principles for Medical Research Involving Human Subjects (Fortaleza, Brazil; October 2013), the Harmonized Tripartite Guidelines for Good Clinical Practice, and applicable regulatory requirements.

The study was not started until approval by the ethics committee and other pertinent authorities was obtained. By signing the protocol, the investigator agreed to adhere to the instructions and procedures described in the protocol and, therefore, to comply with the principles of good clinical practice they entail.

Eligible patients were only included in the study after providing written (witnessed, where required by law or regulation), IEC-approved informed consent, or, if incapable of doing so, after such consent was provided by a legally acceptable representative of the patient. In cases where the patient's representative gave consent, the patient was informed about the study to the extent possible, given his/her understanding. Informed consent was obtained before conducting any study-specific procedures (i.e., all procedures described in the protocol). The process of obtaining informed consent was documented in the patient's source documents.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	09 February 2021
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	Spain: 65
Worldwide total number of subjects	65
EEA total number of subjects	65

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)	50
Adolescents (12-17 years)	15
Adults (18-64 years)	0
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

Between March 2021 and November 2022, a total of 65 patients were enrolled in this trial, of which 6 were considered screening failures. Fifty-nine (59) patients were finally randomized: 42 to bilastine group and 17 to placebo group, which formed the Full Analysis population.

Pre-assignment

Screening details:

This study has been performed in children and adolescent patients aged 2 to under 18 years with a documented history of SAC and/or PAC, documented positive skin prick test and/or positive validated IgE test to seasonal and/or perennial allergen within 6 months before, and signs and symptoms of AC that are likely to continue for the next weeks.

Period 1

Period 1 title	Overall trial (overall period)
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator

Blinding implementation details:

Treatment was double-blind. Bilastine ophthalmic solution 0.6% and placebo were identical in color and appearance. The packaging and labelling did not allow for any distinction between the test and the reference drug. No person involved in conducting the clinical trial was allowed to have access to the randomisation code before the blind was officially broken. Unblinding was not done unless an actual emergency occurred, and knowledge of the patient's treatment affected his/her medical treatment.

Arms

Are arms mutually exclusive?	Yes
Arm title	Bilastine ophthalmic solution 0.6%

Arm description:

In this clinical trial, patients aged 2 to under 18 years with AC could be included and randomised in a 2:1 ratio to treatment with Bilastine ophthalmic solution 0.6% or placebo for 57 days. Patients were divided into cohorts by age (2 to under 6 years [Coh.1], 6 to under 12 years [Coh. 2], 12 to under 18 years [Coh. 3]). Patients were also stratified by indication (SAC or PAC), but no minimum or balanced number of patients in each subgroup was required for analysis.

Arm type	Experimental
Investigational medicinal product name	Bilastine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Eye drops, solution
Routes of administration	Ocular use

Dosage and administration details:

The active substance in this study was Bilastine ophthalmic solution 0.6% (6 mg/mL), 1 drop instilled in each eye once daily.

Arm title	Placebo ophthalmic solution
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Arm description:

In this clinical trial, patients aged 2 to under 18 years with AC could be included and randomised in a 2:1 ratio to treatment with Bilastine ophthalmic solution 0.6% or placebo for 57 days. Patients were divided into cohorts by age (2 to under 6 years [Coh.1], 6 to under 12 years [Coh. 2], 12 to under 18 years [Coh. 3]). Patients were also stratified by indication (SAC or PAC), but no minimum or balanced number of patients in each subgroup was required for analysis.

Arm type	Placebo
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Investigational medicinal product name	ophthalmic solution
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Eye drops, solution
Routes of administration	Ophthalmic use

Dosage and administration details:

The reference therapy in this study was Placebo ophthalmic solution 1 drop instilled in each eye once daily.

Number of subjects in period 1^[1]	Bilastine ophthalmic solution 0.6%	Placebo ophthalmic solution
Started	42	17
Completed	34	12
Not completed	8	5
Consent withdrawn by subject	1	1
Adverse event, non-fatal	3	2
Other reasons	1	1
Lost to follow-up	-	1
Use of prohibited concomitant medications	2	-
Lack of efficacy	1	-

Notes:

[1] - The number of subjects reported to be in the baseline period are not the same as the worldwide number enrolled in the trial. It is expected that these numbers will be the same.

Justification: There were 6 patients who were considered screening failures: 2 patients did not meet at least one of the inclusion criteria, 1 patient met at least one of the exclusion criteria, 1 patient withdrawal of informed consent, and 2 patients for other reasons.

Baseline characteristics

Reporting groups

Reporting group title	Bilastine ophthalmic solution 0.6%
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Reporting group description:

In this clinical trial, patients aged 2 to under 18 years with AC could be included and randomised in a 2:1 ratio to treatment with Bilastine ophthalmic solution 0.6% or placebo for 57 days. Patients were divided into cohorts by age (2 to under 6 years [Coh.1], 6 to under 12 years [Coh. 2], 12 to under 18 years [Coh. 3]). Patients were also stratified by indication (SAC or PAC), but no minimum or balanced number of patients in each subgroup was required for analysis.

Reporting group title	Placebo ophthalmic solution
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Reporting group description:

In this clinical trial, patients aged 2 to under 18 years with AC could be included and randomised in a 2:1 ratio to treatment with Bilastine ophthalmic solution 0.6% or placebo for 57 days. Patients were divided into cohorts by age (2 to under 6 years [Coh.1], 6 to under 12 years [Coh. 2], 12 to under 18 years [Coh. 3]). Patients were also stratified by indication (SAC or PAC), but no minimum or balanced number of patients in each subgroup was required for analysis.

Reporting group values	Bilastine ophthalmic solution 0.6%	Placebo ophthalmic solution	Total
Number of subjects	42	17	59
Age categorical			
Units: Subjects			
Cohort 1 (≥ 2 , < 6)	4	2	6
Cohort 2 (≥ 6 , < 12)	28	11	39
Cohort 3 (≥ 12 , < 18)	10	4	14
Age continuous			
Units: years			
arithmetic mean	10.4	9.3	
standard deviation	± 2.69	± 3.76	-
Gender categorical			
Units: Subjects			
Female	19	3	22
Male	23	14	37
Race			
Units: Subjects			
White	30	13	43
Asian	1	1	2
Black	2	0	2
Other	9	3	12
Type of allergic conjunctivitis			
Units: Subjects			
Perennial allergic conjunctivitis (PAC)	31	14	45
Seasonal allergic conjunctivitis (SAC)	11	3	14

End points

End points reporting groups

Reporting group title	Bilastine ophthalmic solution 0.6%
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Reporting group description:

In this clinical trial, patients aged 2 to under 18 years with AC could be included and randomised in a 2:1 ratio to treatment with Bilastine ophthalmic solution 0.6% or placebo for 57 days. Patients were divided into cohorts by age (2 to under 6 years [Coh.1], 6 to under 12 years [Coh. 2], 12 to under 18 years [Coh. 3]). Patients were also stratified by indication (SAC or PAC), but no minimum or balanced number of patients in each subgroup was required for analysis.

Reporting group title	Placebo ophthalmic solution
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Reporting group description:

In this clinical trial, patients aged 2 to under 18 years with AC could be included and randomised in a 2:1 ratio to treatment with Bilastine ophthalmic solution 0.6% or placebo for 57 days. Patients were divided into cohorts by age (2 to under 6 years [Coh.1], 6 to under 12 years [Coh. 2], 12 to under 18 years [Coh. 3]). Patients were also stratified by indication (SAC or PAC), but no minimum or balanced number of patients in each subgroup was required for analysis.

Primary: Patients with at least one ocular r-TEAE

End point title	Patients with at least one ocular r-TEAE ^[1]
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End point description:

End point type	Primary
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End point timeframe:

Throughout the study.

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: There is no statistical analyses for the primary endpoint since it is a descriptive analyses.

End point values	Bilastine ophthalmic solution 0.6%	Placebo ophthalmic solution		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	42	17		
Units: patients	0	1		

Statistical analyses

No statistical analyses for this end point

Secondary: Patients with at least one TEAE

End point title	Patients with at least one TEAE
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End point description:

End point type	Secondary
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End point timeframe:

Throughout the study.

End point values	Bilastine ophthalmic solution 0.6%	Placebo ophthalmic solution		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	42	17		
Units: patients with at least one event	10	4		

Statistical analyses

No statistical analyses for this end point

Secondary: Patients with at least one ocular TEAE

End point title	Patients with at least one ocular TEAE
End point description:	
End point type	Secondary
End point timeframe:	
Throughout the study.	

End point values	Bilastine ophthalmic solution 0.6%	Placebo ophthalmic solution		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	42	17		
Units: patients	7	3		

Statistical analyses

No statistical analyses for this end point

Secondary: Patients with at least one r-TEAE

End point title	Patients with at least one r-TEAE
End point description:	
End point type	Secondary
End point timeframe:	
Throughout the study	

End point values	Bilastine ophthalmic solution 0.6%	Placebo ophthalmic solution		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	42	17		
Units: patients	0	1		

Statistical analyses

No statistical analyses for this end point

Secondary: Incidence of clinically abnormal findings in ophthalmic examinations

End point title	Incidence of clinically abnormal findings in ophthalmic examinations
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End point description:

Clinical significant (CS) abnormal finding

End point type	Secondary
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End point timeframe:

Visit 1a and visit 5b.

End point values	Bilastine ophthalmic solution 0.6%	Placebo ophthalmic solution		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	42 ^[2]	17 ^[3]		
Units: Number of CS abnormal findings				
number (not applicable)				
Best-Corrected Visual Acuity, V1a (N1=41; N2=17)	0	0		
Best-Corrected Visual Acuity, V5b (N1=34; N2=12)	0	0		
Slit lamp (Cornea), V1a (N1=82; N2=34)	4	0		
Slit lamp (Cornea), V5b (N1=68; N2=24)	0	2		
Slit lamp (Conjunctiva), V1a (N1=82; N2=34)	28	10		
Slit lamp (Conjunctiva), V5b (N1=68; N2=24)	15	6		
Slit lamp (Crystalline lens), V1a (N1=82; N2=34)	0	0		
Slit lamp (Crystalline lens), V5b (N1=68; N2=24)	0	0		
Slit lamp (Eyelid), V1a (N1=82; N2=34)	3	0		
Slit lamp (Eyelid), V5b (N1=68; N2=24)	0	0		
Slit lamp (Ant. chamber), V1a (N1=82; N2=34)	0	0		
Slit lamp (Ant. chamber), V5b (N1=68; N2=24)	0	0		

Notes:

[2] - Number of patients indicated in every visit. N1: bilastine arm; N2: placebo arm.

[3] - Number of patients indicated in every visit. N1: bilastine arm; N2: placebo arm.

Statistical analyses

No statistical analyses for this end point

Secondary: Intraocular pressure (IOP)

End point title	Intraocular pressure (IOP)
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End point description:

End point type	Secondary
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End point timeframe:

V1a and V5b

End point values	Bilastine ophthalmic solution 0.6%	Placebo ophthalmic solution		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	42 ^[4]	17 ^[5]		
Units: mmHg				
arithmetic mean (standard deviation)				
V1a (N1=35; N2=12)	14.71 (± 2.197)	16.25 (± 2.454)		
V5b (N1=29; N2=9)	14.45 (± 2.273)	14.72 (± 2.293)		

Notes:

[4] - Number of patients indicated in every visit. N1: bilastine arm; N2: placebo arm.

[5] - Number of patients indicated in every visit. N1: bilastine arm; N2: placebo arm.

Statistical analyses

No statistical analyses for this end point

Secondary: Peak ocular discomfort

End point title	Peak ocular discomfort
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End point description:

Patients with no or slight ocular discomfort (scores 0-2).

V1b_0= immediately after IMP; V1b_+1= 1 minute after IMP; V1b_+5= 5 minutes after IMP; V5a_0= immediately after IMP; V5a_+1= 1 minute after IMP; V5a_+5= 5 minutes after IMP.

End point type	Secondary
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End point timeframe:

V1b and V5a

End point values	Bilastine ophthalmic solution 0.6%	Placebo ophthalmic solution		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	42 ^[6]	17 ^[7]		
Units: Percentage of patients				
number (not applicable)				
V1b_0 (N1=42; N2=17)	78.5	82.3		
V1b_+1 (N1=42; N2=17)	92.9	100		
V1b_+5 (N1=42; N2=17)	92.9	100		
V5a_0 (N1=32; N2=12)	87.5	100		
V5a_+1 (N1=32; N2=12)	87.5	100		
V5a_+5 (N1=32; N2=12)	87.5	100		

Notes:

[6] - Number of patients indicated in every visit. N1: bilastine arm; N2: placebo arm.

[7] - Number of patients indicated in every visit. N1: bilastine arm; N2: placebo arm.

Statistical analyses

No statistical analyses for this end point

Secondary: Ocular Tolerability

End point title	Ocular Tolerability
End point description:	
Patients with no or slight ocular symptoms (scores from 0-2).	
End point type	Secondary
End point timeframe:	
V1b and V5a	

End point values	Bilastine ophthalmic solution 0.6%	Placebo ophthalmic solution		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	42 ^[8]	17 ^[9]		
Units: percentage of patients				
number (not applicable)				
Burning, V1b (N1=42; N2=17)	88	94.2		
Burning, V5a (N1=33; N2= 12)	90.9	100		
Stinging, V1b (N1=42; N2=17)	87.5	94.2		
Stinging, V5a (N1=33; N2= 12)	97	100		
Tearing, V1b (N1=42; N2=17)	92.8	88.3		
Tearing, V5a (N1=33; N2= 12)	90.9	91.7		
Blurring, V1b (N1=42; N2=17)	95.2	94.1		
Blurring, V5a (N1=33; N2= 12)	96.9	100		
Stickiness, V1b (N1=42; N2=17)	90.5	94.1		
Stickiness, V5a (N1=33; N2= 12)	87.9	75		

Notes:

[8] - Number of patients indicated in every visit. N1: bilastine arm; N2: placebo arm.

[9] - Number of patients indicated in every visit. N1: bilastine arm; N2: placebo arm.

Statistical analyses

No statistical analyses for this end point

Secondary: Summary of TESS

End point title	Summary of TESS
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End point description:

End point type	Secondary
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End point timeframe:

8-weeks study period

End point values	Bilastine ophthalmic solution 0.6%	Placebo ophthalmic solution		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	42 ^[10]	17 ^[11]		
Units: Score				
arithmetic mean (standard deviation)				
Baseline (N1=42; N2=17)	18.7 (± 5.25)	19.0 (± 5.06)		
Overall (N1=38; N2=16)	4.5 (± 4.22)	3.8 (± 4.16)		

Notes:

[10] - Number of patients indicated in every visit. N1: bilastine arm; N2: placebo arm.

[11] - Number of patients indicated in every visit. N1: bilastine arm; N2: placebo arm.

Statistical analyses

Statistical analysis title	MMRM Analysis
Comparison groups	Bilastine ophthalmic solution 0.6% v Placebo ophthalmic solution
Number of subjects included in analysis	59
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.651
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	0.556
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.897
upper limit	3.009

Secondary: Absolute Change from Baseline

End point title	Absolute Change from Baseline
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End point description:

End point type	Secondary
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End point timeframe:
8-weeks study period

End point values	Bilastine ophthalmic solution 0.6%	Placebo ophthalmic solution		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	38	16		
Units: score				
arithmetic mean (standard deviation)	-15.7 (± 9.53)	-15.4 (± 5.22)		

Statistical analyses

Statistical analysis title	MMRM Analysis
Comparison groups	Bilastine ophthalmic solution 0.6% v Placebo ophthalmic solution
Number of subjects included in analysis	54
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.651
Method	Mixed models analysis
Parameter estimate	Median difference (final values)
Point estimate	0.556
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.897
upper limit	3.009

Secondary: Relative Change from Baseline (%)

End point title	Relative Change from Baseline (%)
End point description:	
End point type	Secondary
End point timeframe:	
8-weeks study period	

End point values	Bilastine ophthalmic solution 0.6%	Placebo ophthalmic solution		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	38	16		
Units: percentage				
arithmetic mean (standard deviation)	-76.2 (± 21.61)	-81.0 (± 20.13)		

Statistical analyses

Statistical analysis title	MMRM Analysis
Comparison groups	Bilastine ophthalmic solution 0.6% v Placebo ophthalmic solution
Number of subjects included in analysis	54
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.447
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	4.943
Confidence interval	
level	95 %
sides	2-sided
lower limit	-8.01
upper limit	17.895

Secondary: Summary of TESS from baseline at each week

End point title	Summary of TESS from baseline at each week
End point description:	
End point type	Secondary
End point timeframe:	
8-weeks period	

End point values	Bilastine ophthalmic solution 0.6%	Placebo ophthalmic solution		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	42 ^[12]	17 ^[13]		
Units: Score				
arithmetic mean (standard deviation)				
Baseline (N1=42; N2=17)	18.7 (± 5.25)	19.0 (± 5.06)		
Week 1 (N1=36; N2=15)	5.4 (± 4.86)	5.9 (± 6.31)		
Week 2 (N1=37; N2=12)	5.8 (± 5.90)	3.1 (± 3.42)		
Week 3 (N1=36; N2=14)	4.6 (± 5.14)	2.7 (± 3.73)		

Week 4 (N1=34; N2=12)	4.0 (± 4.45)	2.7 (± 3.31)		
Week 5 (N1=33; N2=12)	3.1 (± 3.65)	2.4 (± 3.34)		
Week 6 (N1=27; N2=11)	2.9 (± 3.36)	2.1 (± 3.05)		
Week 7 (N1=27; N2=11)	2.6 (± 3.19)	2.8 (± 3.21)		
Week 8 (N1=28; N2=12)	2.5 (± 3.33)	2.5 (± 3.79)		

Notes:

[12] - Number of patients indicated in every visit. N1: bilastine arm; N2: placebo arm.

[13] - Number of patients indicated in every visit. N1: bilastine arm; N2: placebo arm.

Statistical analyses

No statistical analyses for this end point

Secondary: Absolute change from baseline week

End point title	Absolute change from baseline week
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End point description:

End point type	Secondary
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End point timeframe:

8-week study period

End point values	Bilastine ophthalmic solution 0.6%	Placebo ophthalmic solution		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	36	14		
Units: score				
arithmetic mean (standard deviation)				
Week 1	-13.3 (± 7.03)	-13.1 (± 6.33)		
Week 2	-12.8 (± 6.95)	-15.1 (± 4.03)		
Week 3	-13.9 (± 6.53)	-16.3 (± 4.60)		
Week 4	-14.7 (± 6.36)	-15.5 (± 4.05)		
Week 5	-15.6 (± 6.47)	-15.9 (± 3.90)		
Week 6	-16.1 (± 5.87)	-16.2 (± 4.27)		
Week 7	-16.4 (± 5.05)	-15.5 (± 5.48)		
Week 8	-15.7 (± 9.53)	-15.4 (± 5.22)		

Statistical analyses

No statistical analyses for this end point

Secondary: Relative change from baseline week (%)

End point title	Relative change from baseline week (%)
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End point description:

End point type	Secondary
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End point timeframe:

8-weeks study period

End point values	Bilastine ophthalmic solution 0.6%	Placebo ophthalmic solution		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	36	15		
Units: percentage				
arithmetic mean (standard deviation)				
Week 1	-68.3 (± 30.49)	-69.7 (± 30.32)		
Week 2	-67.7 (± 30.60)	-84.5 (± 13.25)		
Week 3	-74.6 (± 27.11)	-87.4 (± 15.10)		
Week 4	-78.0 (± 23.72)	-86.7 (± 12.20)		
Week 5	-81.5 (± 22.45)	-88.9 (± 12.93)		
Week 6	-84.1 (± 18.96)	-90.3 (± 12.32)		
Week 7	-86.8 (± 14.74)	-84.6 (± 14.84)		
Week 8	-86.9 (± 14.97)	-87.2 (± 16.85)		

Statistical analyses

No statistical analyses for this end point

Secondary: Ocular Symptom Scores (Itching)

End point title	Ocular Symptom Scores (Itching)
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End point description:

End point type	Secondary
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End point timeframe:

8-week study period

End point values	Bilastine ophthalmic solution 0.6%	Placebo ophthalmic solution		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	42 ^[14]	17 ^[15]		
Units: score				
arithmetic mean (standard deviation)				
Baseline (N1=42; N2=17)	6.5 (± 1.90)	6.5 (± 2.00)		

Overall (N1=38; N2=16)	1.8 (\pm 1.48)	1.5 (\pm 1.93)		
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Notes:

[14] - Number of patients indicated in every visit. N1: bilastine arm; N2: placebo arm.

[15] - Number of patients indicated in every visit. N1: bilastine arm; N2: placebo arm.

Statistical analyses

No statistical analyses for this end point

Secondary: Ocular Symptom Scores (Redness)

End point title	Ocular Symptom Scores (Redness)
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End point description:

End point type	Secondary
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End point timeframe:

8-weeks study period

End point values	Bilastine ophthalmic solution 0.6%	Placebo ophthalmic solution		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	42 ^[16]	17 ^[17]		
Units: score				
arithmetic mean (standard deviation)				
Baseline (N1=42; N2=17)	6.5 (\pm 1.89)	7.0 (\pm 2.32)		
Overall (N1=38; N2=16)	1.8 (\pm 1.71)	1.4 (\pm 1.31)		

Notes:

[16] - Number of patients indicated in every visit. N1: bilastine arm; N2: placebo arm.

[17] - Number of patients indicated in every visit. N1: bilastine arm; N2: placebo arm.

Statistical analyses

No statistical analyses for this end point

Secondary: Ocular Symptom Scores (Tearing)

End point title	Ocular Symptom Scores (Tearing)
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End point description:

End point type	Secondary
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End point timeframe:

8-weeks study period

End point values	Bilastine ophthalmic solution 0.6%	Placebo ophthalmic solution		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	42 ^[18]	17 ^[19]		
Units: score				
arithmetic mean (standard deviation)				
Baseline (N1=42; N2=17)	5.8 (± 2.7)	5.5 (± 3.1)		
Overall (N1=38; N2=16)	1.1 (± 1.31)	1.0 (± 1.21)		

Notes:

[18] - Number of patients indicated in every visit. N1: bilastine arm; N2: placebo arm.

[19] - Number of patients indicated in every visit. N1: bilastine arm; N2: placebo arm.

Statistical analyses

No statistical analyses for this end point

Secondary: Absolute Change from Baseline

End point title	Absolute Change from Baseline
End point description:	
End point type	Secondary
End point timeframe:	
8-weeks study	

End point values	Bilastine ophthalmic solution 0.6%	Placebo ophthalmic solution		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	38	16		
Units: score				
arithmetic mean (standard deviation)				
Itching	-4.8 (± 2.31)	-5.0 (± 2.65)		
Redness	-4.6 (± 2.30)	-5.6 (± 2.12)		
Tearing	-4.7 (± 2.77)	-4.8 (± 2.77)		

Statistical analyses

No statistical analyses for this end point

Secondary: Relative Change from Baseline (%)

End point title	Relative Change from Baseline (%)
End point description:	
End point type	Secondary
End point timeframe:	
8-weeks study	

End point values	Bilastine ophthalmic solution 0.6%	Placebo ophthalmic solution		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	38	16		
Units: percentage				
number (not applicable)				
Itching	-70.5	-76.4		
Redness	-71.2	-77.4		
Tearing	-78.1	-82.2		

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

8-weeks study period

Assessment type	Systematic
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Dictionary used

Dictionary name	MedDRA
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Dictionary version	25.1
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Reporting groups

Reporting group title	Safety population (Bilastine)
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Reporting group description: -

Reporting group title	Safety population (Placebo)
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Reporting group description: -

Serious adverse events	Safety population (Bilastine)	Safety population (Placebo)	
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 42 (0.00%)	0 / 17 (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: 1 %

Non-serious adverse events	Safety population (Bilastine)	Safety population (Placebo)	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	10 / 42 (23.81%)	4 / 17 (23.53%)	
Injury, poisoning and procedural complications			
Allergy to vaccine			
subjects affected / exposed	1 / 42 (2.38%)	0 / 17 (0.00%)	
occurrences (all)	1	0	
Surgical and medical procedures			
Tonsillectomy			
subjects affected / exposed	1 / 42 (2.38%)	0 / 17 (0.00%)	
occurrences (all)	1	0	
Eye disorders			
Conjunctivitis			

subjects affected / exposed	2 / 42 (4.76%)	1 / 17 (5.88%)	
occurrences (all)	2	1	
Blepharitis			
subjects affected / exposed	0 / 42 (0.00%)	1 / 17 (5.88%)	
occurrences (all)	0	1	
Conjunctival hyperaemia			
subjects affected / exposed	1 / 42 (2.38%)	0 / 17 (0.00%)	
occurrences (all)	1	0	
Eye irritation			
subjects affected / exposed	1 / 42 (2.38%)	0 / 17 (0.00%)	
occurrences (all)	1	0	
Eyelid oedema			
subjects affected / exposed	0 / 42 (0.00%)	1 / 17 (5.88%)	
occurrences (all)	0	1	
Ocular discomfort			
subjects affected / exposed	1 / 42 (2.38%)	0 / 17 (0.00%)	
occurrences (all)	1	0	
Ocular hyperaemia			
subjects affected / exposed	1 / 42 (2.38%)	0 / 17 (0.00%)	
occurrences (all)	1	0	
Scleral oedema			
subjects affected / exposed	0 / 42 (0.00%)	1 / 17 (5.88%)	
occurrences (all)	0	1	
Skin and subcutaneous tissue disorders			
Erythema			
subjects affected / exposed	1 / 42 (2.38%)	0 / 17 (0.00%)	
occurrences (all)	1	0	
Infections and infestations			
COVID-19			
subjects affected / exposed	1 / 42 (2.38%)	1 / 17 (5.88%)	
occurrences (all)	1	1	
H1N1 influenza			
subjects affected / exposed	1 / 42 (2.38%)	1 / 17 (5.88%)	
occurrences (all)	1	1	
Conjunctivitis			

subjects affected / exposed	1 / 42 (2.38%)	0 / 17 (0.00%)	
occurrences (all)	1	0	

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
04 December 2020	Expansion of participating sites. Changes to the financial report.
24 February 2021	Expansion of participating sites.
23 June 2021	Expansion of participating sites.
29 December 2021	Expansion of participating sites. Changes to the financial report.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported