



## Clinical trial results:

### **RANDOMIZED CONTROLLED CLINICAL STUDY ON THE EFFICACY AND TOLERABILITY OF 0.4% HYALURONIC ACID HYPOTONIC EYE DROPS (IALUREX) VS. HYDROXYPROPYL-GUAR EYE DROPS (SYSTANE) IN THE TREATMENT OF DRY EYE SYNDROME**

#### **Summary**

EudraCT number	2007-005882-37
Trial protocol	IT
Global end of trial date	05 January 2009

#### **Results information**

Result version number	v1 (current)
This version publication date	03 January 2020
First version publication date	03 January 2020

#### **Trial information**

##### **Trial identification**

Sponsor protocol code	524
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##### **Additional study identifiers**

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

Notes:

##### **Sponsors**

Sponsor organisation name	Bausch & Lomb Group
Sponsor organisation address	Via Pasubio 34, Macherio, Italy, 20050
Public contact	Clinical Science Manager, Bausch & Lomb, + 39 03920731,
Scientific contact	Clinical Science Manager, Bausch & Lomb, + 39 03920731,

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?	No

Notes:

## Results analysis stage

Analysis stage	Final
Date of interim/final analysis	05 January 2009
Is this the analysis of the primary completion data?	Yes
Primary completion date	05 January 2009
Global end of trial reached?	Yes
Global end of trial date	05 January 2009
Was the trial ended prematurely?	No

Notes:

## General information about the trial

Main objective of the trial:

Efficacy of Ialurex vs. Systane Eye Drops on the basis of the improvement of corneal fluorescein staining

Protection of trial subjects:

This clinical investigation was conducted in accordance with the protocol, ICH guidelines (CPMP/ICH/135/95), GCPs, applicable local regulations of Italian Legislative Decrees 211/2003 and 219/2006, and the Declaration of Helsinki (2004).

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	20 May 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	Italy: 43
Worldwide total number of subjects	43
EEA total number of subjects	43

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)	0
Adults (18-64 years)	30
From 65 to 84 years	13
85 years and over	0

## Subject disposition

### Recruitment

Recruitment details: -

### Pre-assignment

Screening details:

Informed consent, eligibility determination, medical history, recording of concomitant medication, demographic data, external eye examination, slit lamp examination, natural and best-corrected visual acuity (BCVA).

### Period 1

Period 1 title	Randomized (overall period)
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Not blinded

### Arms

Are arms mutually exclusive?	Yes
<b>Arm title</b>	Ialurex

Arm description: -

Arm type	Experimental
Investigational medicinal product name	hypotonic 0.4% hyaluronic acid eye drop
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Eye drops
Routes of administration	Ocular use

Dosage and administration details:

1 drop/eye four times a day (4 hours interval)

<b>Arm title</b>	Systane
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Arm description: -

Arm type	Active comparator
Investigational medicinal product name	Hydroxypropyl-Guar Eye
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Eye drops
Routes of administration	Ocular use

Dosage and administration details:

1 drop/eye four times a day (4 hours interval)

<b>Number of subjects in period 1<sup>[1]</sup></b>	Ialurex	Systane
Started	20	18
Completed	20	18

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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: 43 subjects enrolled in this study. Three subjects were screened but not randomized.

## Baseline characteristics

### Reporting groups

Reporting group title	Ialurex
Reporting group description: -	
Reporting group title	Systane
Reporting group description: -	

Reporting group values	Ialurex	Systane	Total
Number of subjects	20	18	38
Age categorical Units: Subjects			
In utero			0
Preterm newborn infants (gestational age < 37 wks)			0
Newborns (0-27 days)			0
Infants and toddlers (28 days-23 months)			0
Children (2-11 years)			0
Adolescents (12-17 years)			0
Adults (18-64 years)			0
From 65-84 years			0
85 years and over			0
Age continuous Units: years			
arithmetic mean	57.6	53.2	
standard deviation	± 16.7	± 18.2	-
Gender categorical Units: Subjects			
Female	15	14	29
Male	5	4	9
Fluorescein Staining Units: total score for degree of corneal stain			
arithmetic mean	4.5	5.4	
standard deviation	± 1.5	± 2.7	-

## End points

### End points reporting groups

Reporting group title	Ialurex
Reporting group description: -	
Reporting group title	Systane
Reporting group description: -	

### Primary: Fluorescein Staining at Visit 4 (Month 2)

End point title	Fluorescein Staining at Visit 4 (Month 2)
End point description:	
End point type	Primary
End point timeframe:	
2 months	

End point values	Ialurex	Systane		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	20	18		
Units: score				
arithmetic mean (standard deviation)	4.5 ( $\pm$ 1.5)	5.4 ( $\pm$ 2.7)		

### Statistical analyses

Statistical analysis title	Difference in Fluorescein Staining change
Comparison groups	Ialurex v Systane
Number of subjects included in analysis	38
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.547
Method	Wilcoxon (Mann-Whitney)

## Adverse events

### Adverse events information

Timeframe for reporting adverse events:

The period of observation for collection of AEs extended from the time the subject gave informed consent until the last study visit.

Assessment type	Non-systematic
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### Dictionary used

Dictionary name	MedDRA
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Dictionary version	9
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### Reporting groups

Reporting group title	Ialurex
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Reporting group description: -

Reporting group title	Systane
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Reporting group description: -

Serious adverse events	Ialurex	Systane	
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 20 (0.00%)	0 / 18 (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: 0 %

Non-serious adverse events	Ialurex	Systane	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	3 / 20 (15.00%)	4 / 18 (22.22%)	
Investigations			
Intra-ocular pressure increased			
subjects affected / exposed	1 / 20 (5.00%)	0 / 18 (0.00%)	
occurrences (all)	1	0	
Eye disorders			
Conjunctival disorder			
subjects affected / exposed	1 / 20 (5.00%)	3 / 18 (16.67%)	
occurrences (all)	1	4	
Conjunctival hyperaemia			
subjects affected / exposed	1 / 20 (5.00%)	1 / 18 (5.56%)	
occurrences (all)	1	2	





## More information

### Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? No

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### Interruptions (globally)

Were there any global interruptions to the trial? No

### Limitations and caveats

None reported