



## Clinical trial results:

**An open, non-randomized study on the effect of preservative free tafluprost (Saflutan® Augentropfen) in patients with ocular hypertension or with primary open angle glaucoma with an uncontrolled intraocular pressure of 30 mmHg and more**

### Summary

EudraCT number	2013-003157-16
Trial protocol	AT
Global end of trial date	01 April 2014

### Results information

Result version number	v1 (current)
This version publication date	19 March 2016
First version publication date	19 March 2016
Summary attachment (see zip file)	Publication (IJOES-2332-290X-S1-006.pdf)

### Trial information

#### Trial identification

Sponsor protocol code	OPHT-260213
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#### Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT01979913
WHO universal trial number (UTN)	-

Notes:

### Sponsors

Sponsor organisation name	Ordination Dr. Hommer
Sponsor organisation address	Albertgasse 39, Vienna, Austria, 1080
Public contact	Dr. Anton Hommer, Ordination Dr. Hommer, +43 1408347715,
Scientific contact	Dr. Anton Hommer, Ordination Dr. Hommer, +43 1408347715,

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	22 September 2014
Is this the analysis of the primary completion data?	Yes
Primary completion date	01 April 2014
Global end of trial reached?	Yes
Global end of trial date	01 April 2014
Was the trial ended prematurely?	No

Notes:

## General information about the trial

Main objective of the trial:

To investigate the effect of saflutan eye drops on intraocular pressure

Protection of trial subjects:

Measurement of intraocular pressure

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	14 October 2013
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	Austria: 16
Worldwide total number of subjects	16
EEA total number of subjects	16

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)	7
From 65 to 84 years	9
85 years and over	0

## Subject disposition

### Recruitment

Recruitment details:

A total of 17 patients was recruited and screened. 16 of them were included in the study, since 1 patient did not fulfill all inclusion criteria.

### Pre-assignment

Screening details: -

### Pre-assignment period milestones

Number of subjects started	16
Number of subjects completed	16

### Period 1

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

### Arms

<b>Arm title</b>	Patients with glaucoma or ocular hypertension
Arm description: -	
Arm type	Experimental
Investigational medicinal product name	Saflutan
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Eye drops
Routes of administration	Ocular use

Dosage and administration details:

1 drop (0.3ml)/day

<b>Number of subjects in period 1</b>	Patients with glaucoma or ocular hypertension
Started	16
Completed	16

## Baseline characteristics

### Reporting groups

Reporting group title	Treatment period
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Reporting group description: -

Reporting group values	Treatment period	Total	
Number of subjects	16	16	
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	62.3		
standard deviation	± 11.8	-	
Gender categorical			
Units: Subjects			
Female	8	8	
Male	8	8	
Intraocular pressure after the washout period in the morning			
Baseline value for IOP in the morning			
Units: mmHg			
arithmetic mean	35.6		
standard deviation	± 4.5	-	
Intraocular pressure after the washout period in the evening			
Baseline value for IOP in the evening			
Units: mmHg			
arithmetic mean	32.9		
standard deviation	± 5.4	-	

## End points

### End points reporting groups

Reporting group title	Patients with glaucoma or ocular hypertension
Reporting group description: -	

### Primary: Intraocular pressure after 8 weeks treatment in the morning

End point title	Intraocular pressure after 8 weeks treatment in the morning <sup>[1]</sup>
End point description:	

End point type	Primary
End point timeframe: 8 weeks	

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: Please see attached reference

<b>End point values</b>	Patients with glaucoma or ocular hypertension			
Subject group type	Reporting group			
Number of subjects analysed	16			
Units: mmHg				
arithmetic mean (standard deviation)	24.3 (± 4.6)			

### Statistical analyses

No statistical analyses for this end point

### Primary: Intraocular pressure after 8 weeks treatment in the evening

End point title	Intraocular pressure after 8 weeks treatment in the evening <sup>[2]</sup>
End point description:	

End point type	Primary
End point timeframe: 8 weeks	

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: Please see attached reference

<b>End point values</b>	Patients with glaucoma or ocular hypertension			
Subject group type	Reporting group			
Number of subjects analysed	16			
Units: mmHg				
arithmetic mean (standard deviation)	21.9 (± 3.9)			

### Statistical analyses

No statistical analyses for this end point

### Secondary: Intraocular pressure after 4 weeks treatment in the morning

End point title	Intraocular pressure after 4 weeks treatment in the morning
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End point description:

End point type	Secondary
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End point timeframe:

4 weeks

<b>End point values</b>	Patients with glaucoma or ocular hypertension			
Subject group type	Reporting group			
Number of subjects analysed	16			
Units: mmHg				
arithmetic mean (standard deviation)	24.4 (± 4.6)			

### Statistical analyses

No statistical analyses for this end point

### Secondary: Intraocular pressure after 4 weeks treatment in the evening

End point title	Intraocular pressure after 4 weeks treatment in the evening
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End point description:

End point type	Secondary
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End point timeframe:

4 weeks

<b>End point values</b>	Patients with glaucoma or ocular hypertension			
Subject group type	Reporting group			
Number of subjects analysed	16			
Units: mmHg				
arithmetic mean (standard deviation)	21.6 (± 4.6)			

### Statistical analyses

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No statistical analyses for this end point

## Adverse events

### Adverse events information

Timeframe for reporting adverse events:

During the whole treatment period

Assessment type	Systematic
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### Dictionary used

Dictionary name	MedlinePlus
Dictionary version	18.04.12

### Reporting groups

Reporting group title	Patients included in the study
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Reporting group description: -

<b>Serious adverse events</b>	Patients included in the study		
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 16 (0.00%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events	0		

Frequency threshold for reporting non-serious adverse events: 0 %

<b>Non-serious adverse events</b>	Patients included in the study		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	8 / 16 (50.00%)		
Eye disorders			
Pruritus	Additional description: Itching after instillation		
subjects affected / exposed	1 / 16 (6.25%)		
occurrences (all)	1		
Hyperemia	Additional description: Conjunctival hyperemia in both eyes		
subjects affected / exposed	1 / 16 (6.25%)		
occurrences (all)	1		
Burning sensation	Additional description: Burning after instillation		
subjects affected / exposed	1 / 16 (6.25%)		
occurrences (all)	1		
Photophobia	Additional description: Light sensitivity		

subjects affected / exposed occurrences (all)	1 / 16 (6.25%) 1		
Blepharitis subjects affected / exposed occurrences (all)	1 / 16 (6.25%) 1		
Respiratory, thoracic and mediastinal disorders			
Common cold subjects affected / exposed occurrences (all)	2 / 16 (12.50%) 2		
Rhinitis subjects affected / exposed occurrences (all)	1 / 16 (6.25%) 2		
Skin and subcutaneous tissue disorders			
Gingivitis subjects affected / exposed occurrences (all)	1 / 16 (6.25%) 1		
Stomal mucosa wound subjects affected / exposed occurrences (all)	1 / 16 (6.25%) 1		
Exanthema and pruritus subjects affected / exposed occurrences (all)	1 / 16 (6.25%) 1	Additional description: Exanthema and pruritus (limbs)	

## **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