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

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

Arm title	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

Number of subjects in period 1	Patients with glaucoma or ocular hypertension
Started	16
Completed	16

Baseline characteristics

Reporting groups

Reporting group title	Treatment period

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[1]

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

End point values	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[2]

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

End point values	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

End point description:

End point type	Secondary

End point timeframe:

4 weeks

End point values	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

End point description:

End point type	Secondary

End point timeframe:

4 weeks

End point values	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

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
Dictionary used	
Dictionary name	MedlinePlus
Dictionary version	18.04.12
Reporting groups	
Reporting group title	Patients included in the study

Reporting group description: -

Serious adverse events	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 %

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

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