Clinical trial results:
An open, non-randomized study on the effect of changing from preserved prostaglandin formulations to preservative free tafluprost (Saflutan® Augentropfen) in patients with ocular hypertension or primary open angle glaucoma on tear film thickness

Summary

EudraCT number	2015-004012-37
Trial protocol	AT
Global end of trial date	25 April 2017

Results information

Result version number	v1 (current)
This version publication date	26 January 2020
First version publication date	26 January 2020

Trial information

Trial identification

Sponsor protocol code	HOM1-2015

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT03204487
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Ordination Dr. Hommer
Sponsor organisation address	Albertgasse 39, Vienna, Austria, 1080
Public contact	Anton Hommer, Ordination Dr. Hommer, a.hommer@aon.at
Scientific contact	Anton Hommer, Ordination Dr. Hommer, a.hommer@aon.at

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	25 April 2017
Is this the analysis of the primary completion data?	Yes
Primary completion date	25 April 2017
Global end of trial reached?	Yes
Global end of trial date	25 April 2017
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To test the hypothesis that changing patients who are on preserved prostaglandin formulations to preservative free tafluprost may be associated with an increase in ocular tear film thickness.

Protection of trial subjects:

Questioning about Adverse Events on the study day.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	01 January 2016
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: 30
Worldwide total number of subjects	30
EEA total number of subjects	30

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)	13
From 65 to 84 years	17
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

Patients were recruited from Ordination Dr. Hommer.

Pre-assignment

Screening details:

All outcome parameters were measured between 8am and 11pm. At baseline, patients were studied after instilling their evening dose of their preserved prostaglandin formulation at the day before. After completion of the baseline visit, eligible patients were switched from preserved prostaglandin formulations to Saflutan® eye drops.

Period 1

Period 1 title	Study 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:

Patients received Saflutan eye drops from Visit 1 to Visit 3.

Arm type	Experimental
Investigational medicinal product name	Saflutan eye drops
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Eye drops
Routes of administration	Ocular use

Dosage and administration details:

1 drop of tafluprost 15µg/ml (Saflutan® 15 Mikrogramm/ml Augentropfen im Einzeldosisbehaltnis, Merck Sharp & Dohme, Wien) once daily in the study eye administered in the evening

Number of subjects in period 1	Patients with glaucoma or ocular hypertension
Started	30
Completed	30

Baseline characteristics

Reporting groups

Reporting group title	Study period

Reporting group description: -

Reporting group values	Study period	Total	
Number of subjects	30	30	
Age categorical Units: Subjects			
In utero	0	0	
Preterm newborn infants (gestational age < 37 wks)	0	0	
Newborns (0-27 days)	0	0	
Infants and toddlers (28 days-23 months)	0	0	
Children (2-11 years)	0	0	
Adolescents (12-17 years)	0	0	
Adults (18-64 years)	13	13	
From 65-84 years	17	17	
85 years and over	0	0	
Gender categorical Units: Subjects			
Female	18	18	
Male	12	12	

Subject analysis sets

Subject analysis set title	Patients included in the study
Subject analysis set type	Per protocol

Subject analysis set description:

Analysis was done per protocol

Reporting group values	Patients included in the study		
Number of subjects	30		
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)	13		
From 65-84 years	17		
85 years and over	0		

Gender categorical Units: Subjects			
Female	18		
Male	12		

End points

End points reporting groups

Reporting group title	Patients with glaucoma or ocular hypertension
Reporting group description: Patients received Saflutan eye drops from Visit 1 to Visit 3.	
Subject analysis set title	Patients included in the study
Subject analysis set type	Per protocol
Subject analysis set description: Analysis was done per protocol	

Primary: Tear Film Thickness

End point title	Tear Film Thickness
End point description:	
End point type	Primary
End point timeframe: Change in tear film thickness from Visit 1 to Visit 3.	

End point values	Patients with glaucoma or ocular hypertension	Patients included in the study		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	30	30		
Units: µm	30	30		

Statistical analyses

Statistical analysis title	Change in TFT
Comparison groups	Patients with glaucoma or ocular hypertension v Patients included in the study
Number of subjects included in analysis	60
Analysis specification	Pre-specified
Analysis type	other
P-value	≤ 0.05
Method	t-test, 2-sided
Parameter estimate	Mean difference (final values)
Confidence interval	
level	95 %
sides	2-sided

Adverse events

Adverse events information	
Timeframe for reporting adverse events: From Screening to last visit.	
Assessment type	Non-systematic
Dictionary used	
Dictionary name	MedDRA
Dictionary version	22.0
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 / 30 (0.00%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events	0		

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

Non-serious adverse events	Patients included in the study		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	27 / 30 (90.00%)		
Vascular disorders			
Arterial hypertension			
subjects affected / exposed	1 / 30 (3.33%)		
occurrences (all)	1		
Cardiac disorders			
Atrial fibrillation			
subjects affected / exposed	1 / 30 (3.33%)		
occurrences (all)	1		
Nervous system disorders			
Headache			
subjects affected / exposed	6 / 30 (20.00%)		
occurrences (all)	6		
Migraine			

subjects affected / exposed	1 / 30 (3.33%)		
occurrences (all)	1		
Eye disorders			
Hyposphagma			
subjects affected / exposed	1 / 30 (3.33%)		
occurrences (all)	1		
Eye irritation			
subjects affected / exposed	1 / 30 (3.33%)		
occurrences (all)	1		
Visual acuity reduced			
subjects affected / exposed	1 / 30 (3.33%)		
occurrences (all)	1		
Vision blurred			
subjects affected / exposed	2 / 30 (6.67%)		
occurrences (all)	2		
eye itching			
subjects affected / exposed	1 / 30 (3.33%)		
occurrences (all)	1		
Foreign body sensation in eyes			
subjects affected / exposed	1 / 30 (3.33%)		
occurrences (all)	1		
burning eyes			
subjects affected / exposed	2 / 30 (6.67%)		
occurrences (all)	1		
Respiratory, thoracic and mediastinal disorders			
Dyspnoea			
subjects affected / exposed	1 / 30 (3.33%)		
occurrences (all)	1		
Rhinitis			
subjects affected / exposed	2 / 30 (6.67%)		
occurrences (all)	2		
Cough			
subjects affected / exposed	1 / 30 (3.33%)		
occurrences (all)	1		
common cold			

subjects affected / exposed occurrences (all)	2 / 30 (6.67%) 1		
Renal and urinary disorders Urinary tract infection subjects affected / exposed occurrences (all)	 1 / 30 (3.33%) 1		
Musculoskeletal and connective tissue disorders Neck pain subjects affected / exposed occurrences (all) Back pain subjects affected / exposed occurrences (all)	 1 / 30 (3.33%) 1 1 / 30 (3.33%) 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