Clinical trial results:
Intraocular pressure and tolerability Study of Preserved Bimatoprost 0.01% (BMD) or Tafluprost Unit Dose Preservative Free 15microgram/ml (TUDPF) (Saflutan), in patients with Ocular hypertension or glaucoma suitable for prostaglandin therapy: A Randomized, single masked, 3 month cross-over, Investigator led, European multicentre Trial, II (SPORT II)

Summary

EudraCT number	2014-004442-10
Trial protocol	BE
Global end of trial date	01 November 2017

Results information

Result version number	v1 (current)
This version publication date	19 February 2021
First version publication date	19 February 2021
Summary attachment (see zip file)	Synopsis (Synopsis SPORT II EN.doc) Study Report SPORT II (CLINICAL STUDY REPORT SPORT II version 1.pdf)

Trial information

Trial identification

Sponsor protocol code	SPORTII

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT02471105
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	University Hospitals of Leuven
Sponsor organisation address	Herestraat 49, Leuven, Belgium, 3000
Public contact	Ingeborg Stalmans, University Hospitals of Leuven, 0032 16332372, ingeborg.stalmans@uzleuven.be
Scientific contact	Ingeborg Stalmans, University Hospitals of Leuven, 0032 16332372, ingeborg.stalmans@uzleuven.be

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	01 November 2017
Is this the analysis of the primary completion data?	Yes
Primary completion date	01 November 2017
Global end of trial reached?	Yes
Global end of trial date	01 November 2017
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The primary objective is to compare the difference in mean IOP values between the 2 groups at 6 months.

Protection of trial subjects:

Patients are treated in routine care. In case of any discomfort or issues interim visits were scheduled.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	28 October 2015
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: 11
Country: Number of subjects enrolled	Belgium: 15
Country: Number of subjects enrolled	Switzerland: 6
Country: Number of subjects enrolled	Italy: 33
Country: Number of subjects enrolled	United Kingdom: 2
Worldwide total number of subjects	67
EEA total number of subjects	61

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)	19
From 65 to 84 years	47
85 years and over	1

Subject disposition

Recruitment

Recruitment details:

The patients are recruited during their routine glaucoma check-ups.
The recruitment period ranges from 1OCT2015 until 30MAR2017.

Pre-assignment

Screening details:

Patients (adults) suffering from ocular hypertension or open angle glaucoma (including those with pseudoexfoliation) and who consented to participate were enrolled in this study. Patients who were on therapy at the screening visit underwent a washout period for 4 weeks (depending on therapy) before baseline visit.

Period 1

Period 1 title	2 study periods of 3 months(crossover) (overall period)
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Single blind
Roles blinded	Investigator[1]

Arms

Are arms mutually exclusive?	Yes
Arm title	Arm A

Arm description:

Patient receives preservative-free tafluprost 15 microgram/ml in period 1 (3 months) followed by bimatoprost 0.1mg/ml with 0.02% benzalkonium chloride (BAK) in period 2 (3 months)

Arm type	Active comparator
Investigational medicinal product name	Saflutan/Lumigan
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Eye drops
Routes of administration	Ophthalmic use

Dosage and administration details:

Instill one eye drop in each eye every night at 8:30 PM.

Arm title	Arm B

Arm description:

Patient receives bimatoprost 0.1mg/ml with 0.02% benzalkonium chloride (BAK) followed by preservative-free tafluprost 15 microgram/ml in period 1 (3 months) in period 2 (3 months)

Arm type	Active comparator
Investigational medicinal product name	Lumigan/Saflutan
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Eye drops
Routes of administration	Ophthalmic use

Dosage and administration details:

Instill one eye drop in each eye every evening at 8:30PM

Notes:

[1] - The roles blinded appear inconsistent with a simple blinded trial.

Justification: This is an investigator-masked study. The subject was not blinded because packaging was visibly different. It was technical not possible to modify the package in such way that patient would be masked.

Number of subjects in period 1	Arm A	Arm B
Started	33	34
Wash-out	33	34
Completed	33	34

Baseline characteristics

Reporting groups	
Reporting group title	2 study periods of 3 months(crossover)
Reporting group description:	
all 67 patients were included in study analysis	

Reporting group values	2 study periods of 3 months(crossover)	Total	
Number of subjects	67	67	
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)	19	19	
From 65-84 years	47	47	
85 years and over	1	1	
Gender categorical Units: Subjects			
Female	33	33	
Male	34	34	

End points

End points reporting groups

Reporting group title	Arm A
Reporting group description:	
Patient receives preservative-free tafluprost 15 microgram/ml in period 1 (3 months) followed by bimatoprost 0.1mg/ml with 0.02% benzalkonium chloride (BAK) in period 2 (3 months)	
Reporting group title	Arm B
Reporting group description:	
Patient receives bimatoprost 0.1mg/ml with 0.02% benzalkonium chloride (BAK) followed by preservative-free tafluprost 15 microgram/ml in period 1 (3 months) in period 2 (3 months)	

Primary: Difference in mean IOP values between the 2 groups at 6 months

End point title	Difference in mean IOP values between the 2 groups at 6 months
End point description:	
The primary endpoint will be the difference in mean IOP values between the 2 groups at 6 months	
End point type	Primary
End point timeframe:	
6 months	

End point values	Arm A	Arm B		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	33	31		
Units: mmHg				
number (not applicable)	33	31		

Statistical analyses

Statistical analysis title	Full analysis set
Comparison groups	Arm B v Arm A
Number of subjects included in analysis	64
Analysis specification	Pre-specified
Analysis type	
P-value	< 0.05
Method	ANOVA
Parameter estimate	Mean difference (final values)

Secondary: Difference in IOP values between the groups in change from baseline IOP at month 3 and month 6

End point title	Difference in IOP values between the groups in change from baseline IOP at month 3 and month 6

End point description:

The difference in IOP values between the groups in change from baseline IOP at month 3 and month 6 respectively;

End point type	Secondary

End point timeframe:

6 months

End point values	Arm A	Arm B		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	33	31		
Units: mmHg				
number (not applicable)	33	31		

Statistical analyses

No statistical analyses for this end point

Secondary: Difference in mean IOP between the 2 groups at 3 months

End point title	Difference in mean IOP between the 2 groups at 3 months

End point description:

The difference in mean IOP between the 2 groups at 3 months

End point type	Secondary

End point timeframe:

3 months

End point values	Arm A	Arm B		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	33	31		
Units: mmHg				
number (not applicable)	33	31		

Statistical analyses

No statistical analyses for this end point

Secondary: difference in IOP between the 2 groups at each timepoints at months 3 and 6

End point title	difference in IOP between the 2 groups at each timepoints at months 3 and 6

End point description:

The difference in IOP between the 2 groups at each timepoints at months 3 and 6;

End point type	Secondary

End point timeframe:

6 months

End point values	Arm A	Arm B		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	33	31		
Units: mmHg				
number (not applicable)	33	31		

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information	
Timeframe for reporting adverse events: 28OCT2015 until 1NOV2017	
Assessment type	Systematic

Dictionary used	
Dictionary name	ICD
Dictionary version	9

Reporting groups	
Reporting group title	Arm A
Reporting group description: -	
Reporting group title	Arm B
Reporting group description: -	

Serious adverse events	Arm A	Arm B	
Total subjects affected by serious adverse events			
subjects affected / exposed	3 / 33 (9.09%)	2 / 34 (5.88%)	
number of deaths (all causes)	0	0	
number of deaths resulting from adverse events	0	0	
Cardiac disorders			
Myocardial infarction	Additional description: Segment elevation myocardial infarction (STEMI)		
subjects affected / exposed	1 / 33 (3.03%)	0 / 34 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory, thoracic and mediastinal disorders			
Continuous positive airway pressure	Additional description: Start of CPAP because of sleepapnea.		
subjects affected / exposed	1 / 33 (3.03%)	0 / 34 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonia			
subjects affected / exposed	0 / 33 (0.00%)	1 / 34 (2.94%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Skin and subcutaneous tissue disorders			
Lichen sclerosus repair			

subjects affected / exposed	1 / 33 (3.03%)	0 / 34 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Endocrine disorders			
Pancreatitis	Additional description: Mild pancreatitis		
subjects affected / exposed	0 / 33 (0.00%)	1 / 34 (2.94%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	

Frequency threshold for reporting non-serious adverse events: 1 %

Non-serious adverse events	Arm A	Arm B	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	10 / 33 (30.30%)	11 / 34 (32.35%)	
General disorders and administration site conditions			
Common cold			
subjects affected / exposed	1 / 33 (3.03%)	1 / 34 (2.94%)	
occurrences (all)	1	1	
Blood and lymphatic system disorders			
Increased arterial hypertension			
subjects affected / exposed	1 / 33 (3.03%)	0 / 34 (0.00%)	
occurrences (all)	1	0	
Eye disorders			
Itching feeling in both eyes			
subjects affected / exposed	0 / 33 (0.00%)	1 / 34 (2.94%)	
occurrences (all)	0	1	
Gritty feeling in both eyes			
subjects affected / exposed	1 / 33 (3.03%)	0 / 34 (0.00%)	
occurrences (all)	1	0	
Worsening of dry feeling in both eyes			
subjects affected / exposed	2 / 33 (6.06%)	0 / 34 (0.00%)	
occurrences (all)	2	0	
Darkening of skin around the eyes			
subjects affected / exposed	0 / 33 (0.00%)	1 / 34 (2.94%)	
occurrences (all)	0	1	
Growth of eye lashes			

subjects affected / exposed	0 / 33 (0.00%)	2 / 34 (5.88%)	
occurrences (all)	0	2	
Posterior capsular fibrosis			
subjects affected / exposed	1 / 33 (3.03%)	0 / 34 (0.00%)	
occurrences (all)	1	0	
Burning sensation in eyes			
subjects affected / exposed	0 / 33 (0.00%)	1 / 34 (2.94%)	
occurrences (all)	0	1	
Rash around eyes			
subjects affected / exposed	0 / 33 (0.00%)	1 / 34 (2.94%)	
occurrences (all)	0	1	
Epitheliopathy			
subjects affected / exposed	1 / 33 (3.03%)	0 / 34 (0.00%)	
occurrences (all)	1	0	
Blepharitis			
subjects affected / exposed	0 / 33 (0.00%)	1 / 34 (2.94%)	
occurrences (all)	0	1	
Conjunctival hyperaemia			
subjects affected / exposed	1 / 33 (3.03%)	0 / 34 (0.00%)	
occurrences (all)	1	0	
Gastrointestinal disorders			
Hernia diaphragmatic			
subjects affected / exposed	0 / 33 (0.00%)	1 / 34 (2.94%)	
occurrences (all)	0	1	
Respiratory, thoracic and mediastinal disorders			
Sleep apnoea syndrome			
subjects affected / exposed	1 / 33 (3.03%)	0 / 34 (0.00%)	
occurrences (all)	1	0	
Bronchitis			
subjects affected / exposed	1 / 33 (3.03%)	0 / 34 (0.00%)	
occurrences (all)	1	0	
Renal and urinary disorders			
Urinary tract infection			
subjects affected / exposed	0 / 33 (0.00%)	1 / 34 (2.94%)	
occurrences (all)	0	1	
Musculoskeletal and connective tissue disorders			

Osteoarthritis in neck subjects affected / exposed occurrences (all)	0 / 33 (0.00%) 0	1 / 34 (2.94%) 1	

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
21 September 2015	Correction of typo in title: Bimatoprost 0.01% instead of 0.1% New full title: Intraocular pressure and tolerability Study of Preserved Bimatoprost 0.01% (BIMMD) or Tafluprost Unit Dose Preservative Free 15microgram/ml (TUDPF) (Saflutan), in patients with Ocular hypertension or glaucoma suitable for prostaglandin therapy: A Randomized, single masked, 3 month cross-over, Investigator led, European multicentre Trial, II (SPORT II)
16 December 2015	Exclusion criteria "History of COPD, Asthma or heart failure" was added to the protocol. The time frame for keeping all study data and documents has been adjusted from 5 to 20 years, in accordance with Belgian legislation and European Directive 2005/28 / EC.
09 June 2016	A sentence has been amended in the Informed Consent Form so that this form is identical to the protocol.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported