An Evaluation of Patient Reported Outcomes and Ocular Surface Health in Patients Using DuoTrav APS Eye Drops Solution Versus XALACOM® Eye Drops Solution.

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A new formulation of DuoTrav® eye drops, called DuoTrav APS, in which, the preservative (BAC) has been replaced by a new preservative called POLYQUAD has been developed. POLYQUAD is expected to be better tolerated in the eye, especially for the...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Glaucoma and ocular hypertension
Study type	Interventional

Summary

ID

NL-OMON35130

Source
ToetsingOnline

Brief title
DuoTrav APS versus XALACOM® in Ocular Surface Health

Condition

- Glaucoma and ocular hypertension

Synonym
raised intra-ocular pressure with optic nerve damage, raised intra-ocular pressure without optic nerve damage

Research involving
Human

Sponsors and support

Primary sponsor: Alcon Laboratories
Source(s) of monetary or material Support: Alcon Research Ltd.

Intervention

Keyword: DuoTrav APS, Ocular Surface Health, Patient reported Outcomes

Outcome measures

Primary outcome

Mean NEI VFQ-25 composite (Visual Function) score at the end of the treatment period (Day 90). A two-sample t-test will be used to test for differences between treatments in the means.

Secondary outcome

Mean OSSG (Ocular Surface Symptoms in Glaucoma) composite score at the end of the treatment period (Day 90). A two-sample t-test will be used to test for differences between treatments in the means for each variable.

Study description

Background summary

Open-angle glaucoma and ocular hypertension are eye conditions associated with abnormally high fluid pressure in the eye (called intraocular pressure or IOP). If left untreated, elevated IOP may eventually cause damage to the optic nerve and a loss of vision. Treatment for both open-angle glaucoma and ocular hypertension is aimed at lowering pressure in the eye and there are different types of medications that can be used to do this. DuoTrav® and XALACOM® are both eye drops that are currently available by prescription for the treatment of high intraocular pressure.
In the marketed products DuoTrav® and XALACOM®, like in most eye drop medications, the preservative used is called benzalkonium chloride (BAC). When used in the eye over very long periods, BAC in eye drops may cause signs or symptoms of eye discomfort in some sensitive patients.

Study objective

A new formulation of DuoTrav® eye drops, called DuoTrav APS, in which, the preservative (BAC) has been replaced by a new preservative called POLYQUAD has been developed. POLYQUAD is expected to be better tolerated in the eye, especially for the patients who are sensitive to BAC. It is also expected to show the same efficacy for lowering IOP as DuoTrav®.

In this research study, we would like to find out if DuoTrav APS is better tolerated in the eye than XALACOM®.

Study design

3 months, two-arm, parallel, multicenter, double-masked, randomized, active controlled study:

DuoTrav APS once daily or
XALACOM® once daily.

Intervention

not applicable

Study burden and risks

In a period of 3 months, patients need to come to the hospital 2 times for an ophthalmic examination and completion of questionnaires (3 questionnaires at Visit 1 and 2 questionnaires at Visit 2). Each visit will take approximately 90 minutes of their time. None of the tests are experimental.
Many patients have already been treated with DuoTrav® and XALACOM® and it has usually been tolerated well. Nevertheless certain side effects similar to those seen with many other eye drops may occur (e.g. red eyes). POLYQUAD at the same strength as in DuoTrav APS has been used for many years in other eye drop products for cleaning contact lenses and relief of dry eye symptoms. No additional side effects related to this ingredient are expected to occur.

Contacts

Public
Alcon Laboratories

Rijksweg 14
2870 Puurs
België

Scientific
Alcon Laboratories

Rijksweg 14
2870 Puurs
België

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

1. Patients * 18 years of age.
2. Must have a clinical diagnosis of open-angle glaucoma (with or without pseudoexfoliation or pigment dispersion component), or ocular hypertension in at least one eye.
3. Must have a corneal fluorescein staining score of * 1 in at least one eye.
4. Must have had their IOP controlled using only the fixed combination XALACOM® for at least 1 continuous month immediately prior to Visit 1 in at least one eye.
5. The IOP should be able to be controlled in the opinion of the Investigator and stable while on fixed combination with the study medication for the eye(s) currently being dosed with XALACOM®
6. Must have an IOP in both eyes that, in the opinion of the investigator, is considered to be stable and safe for the patient.
7. The last dose of XALACOM® must have been instilled within 24 hours of Visit 1.
8. Must be willing and able to discontinue use of any topical ocular medication other than the study medication for the duration of the study.
9. Best-corrected visual acuity score of *55 ETDRS letters read in each eye.
10. Women of childbearing potential must meet all of the following conditions at Visit 1: they are not breast-feeding; they have a negative urine pregnancy test at Visit 1; they agree to undertake a urine pregnancy test upon entering and exiting the study; they are not planning to become pregnant during the course of the study; they are currently using, and agree to continue to use adequate birth control methods for the duration of the study (hormonal, mechanical, surgical or abstinence)

Exclusion criteria

1. Any abnormality preventing reliable applanation tonometry in the study eye(s)
2. Presence of any ocular pathology in either eye seen during the slit lamp or fundus exams, that in the opinion of the Investigator may preclude the safe administration of test article or safe participation in this study.
3. Dry eye or KCS currently being treated with the use of punctal plugs, punctal cautery, Restasis®, or topical ocular corticosteroids.
4. Patients who have undergone keratorefractive ocular laser procedures, corneal surgery or surgery to the corneal surface, including but not limited to LASIK and PRK, within 6 months prior to Visit 1.
5. Any other ocular laser surgery in either eye within 3 months prior to Visit 1.
6. Patients who have undergone intraocular or extra-ocular surgery, in either eye, within 6 months prior to Visit 1.
7. History of progressive retinal or optic nerve disease other than glaucoma.
8. Severe central visual field loss in either eye based upon the clinical judgement of the Investigator.
9. Any history of ocular infections or inflammatory ocular conditions within the past 3 months in either eye.
10. Ocular trauma within 6 months prior to Visit 1 in either eye.
11. History or evidence of corneal transplant or transplant variant procedures.
12. Patients with suspected or diagnosed Sjogren*s syndrome currently being treated with punctual plugs, punctual cautery, other topical ocular medications or the use of systemic therapy.
13. History of or current bronchial asthma, or severe chronic obstructive pulmonary disease.
14. History of or current severe, unstable or uncontrolled cardiovascular, hepatic, or renal disease.
15. History of spontaneous or current hypoglycemia or uncontrolled diabetes.
16. History of or current severe allergic rhinitis and bronchial hyperreactivity.
17. History of intolerance or hypersensitivity to any component of the test articles.
18. Use of any systemic medications on a chronic basis that have not been on a stable dosing regimen for at least 30 days prior to visit 1, or an anticipated change in dosing regimen of medications during the course of the study.
19. Use of ocular medications (including over the counter and prescription medications) other than XALACOM® within 7 days of Visit 1.
20. Use of corticosteroids within 30 days of Visit 1 , or any anticipated use of corticosteroids during the course of the study.
21. Use of contact lenses within 30 days of Visit 1. Concomitant use of contact lenses is also excluded for the duration of the study.
22. Participation in an investigational drug or device study within 30 days of entering this study.

Study design

Design

Study phase:	3
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	04-11-2010
Enrollment:	30
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	DuoTrav APS
Generic name:	travoprost 40 µg/ml / timolol 5 mg/ml Eye Drops, Solution
Product type:	Medicine
Brand name:	XALACOM®
Generic name:	latanoprost 50 µg/ml / timolol 5 mg/ml Eye Drops, Solution
Registration:	Yes - NL intended use

Ethics review

Approved WMO

Date:	19-06-2009
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

Approved WMO Date:	16-09-2009
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	22-02-2010
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	21-04-2010
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	12-07-2010
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	20-07-2010
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	11-02-2011
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	14-02-2011
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
EudraCT	EUCTR2009-010604-29-NL
CCMO	NL28207.068.09