Evaluation of Clinical Outcomes Following Treatment with Systane® Balance in Dry Eye
Subjects with Lipid Deficiency

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The purpose of this research study is to compare Systane Balance Lubricant Eye Drops to Preservative-Free 0.9% Saline as necessary to support Systane Balance reimbursement in France.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Ocular sensory symptoms NEC
Study type	Interventional

Summary

ID

NL-OMON38494

Source
ToetsingOnline

Brief title
Clinical Outcomes Following Treatment with Systane Balance of Dry Eye

Condition

- Ocular sensory symptoms NEC

Synonym
Dry eyes

Research involving
Human

Sponsors and support

Primary sponsor: Alcon Laboratories

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

Intervention

Keyword: Dry Eye, Lipid Deficiency, Tear film break-up time

Outcome measures

Primary outcome

Primary Efficacy:

* Change from baseline in TFBUT at Day 35

Secondary outcome

Secondary Efficacy:

* Change from baseline in Total Ocular Surface Staining (TOSS) score at Day 35

* Change from baseline in OSDI score at Day 35

* Change from baseline in Impact of Dry Eye on Everyday Life (IDEEL) Treatment

Effectiveness score at Day 35

* Change from baseline in IDEEL Treatment Inconvenience score at Day 35

Supportive:

* Change from baseline in MGD score (Expressibility) at Day 35

* Change from baseline in MGD score (Meibum Quality) at Day 35

* Change from baseline in TFBUT at Day 15

* Change from baseline in TOSS score at Day 15

* Change from baseline in MGD score (Expressibility) at Day 15

* Change from baseline in MGD score (Meibum Quality) at Day 15

* Dosing frequency during Treatment Phase II.

Study description

Background summary

The tear film is a thin layer of moisture on the eye composed of a fatty layer (exposed to the air), a viscous (gooey) layer next to the eye and a thicker watery layer in the middle. Lipid deficient dry eye means that there is less of the fatty layer in the tear film. As a result, the watery layer evaporates quicker and the cells on the cornea become exposed to the air which causes the burning, stinging, and redness symptoms. Often the eye responds with symptoms such as itchiness and swelling. Treatment for dry eye disease is aimed at relieving those symptoms. Lubricating eye drops try to replenish the fatty and watery layers of the tear film so the cells on the cornea have less exposure to air.

Study objective

The purpose of this research study is to compare Systane Balance Lubricant Eye Drops to Preservative-Free 0.9% Saline as necessary to support Systane Balance reimbursement in France.

Study design

Approximately 3,5 months (105 days, wash-out included), 2 arms, parallel groups, multicenter, observer masked, randomized study:
* Systane Balance Lubricant Eyedrops (dosed 4x per day for 35 days & as often as needed for an additional 55 days)
or
* Preservative-Free 0.9% Saline (dosed 4x per day for 35 days & as often as needed for an additional 55 days)

Intervention

Not applicable

Study burden and risks

In a period of 3,5 months (105 days) patients need to come to the hospital 5 times for an ophthalmic examination. Each visit will take between 1 and 2 hours of their time. None of the tests are experimental. After a wash-out period (with preservative-Free 0.9% Saline), the subjects will receive orSystane Balance Lubricant Eyedrops (dosed 4x per day for 35 days & as often as needed for an additional 55 days) or Preservative-Free 0.9% Saline (dosed 4x per day for 35 days & as often as needed for an additional 55 days)

There is no increased risk expected with the use of either one of the eye drops used in this study.

The examinations that will be conducted during the study may cause some discomfort.

The yellow dye (fluorescein) and green dye (lissamine) put in the eye for the staining examinations could make the skin and bodily secretions and excretions change color or cause some irritation.

One may experience side effects related to the use of the study eye drops which are expected to be temporary. Many side effects go away after the study eye drops is stopped but, in some cases, the side effects may be serious and/or lasting. Common side effects are listed below but they will vary from person to person.

Vision may be temporarily blurred when these products are first used. Minor eye pain, eye redness, burning, stinging, irritation, watery eyes, unpleasant taste in the mouth and change in vision may temporarily occur. One may also experience continued eye redness and irritation.

Administration of the study drug and/or the examination dyes, like any medication, may cause an allergic reaction. Allergic reactions may be mild (rash, hives) to severe (difficulty breathing, or a collapse of blood circulation and breathing systems). A severe allergic reaction would require immediate medical treatment and could result in permanent disability or death.

Contacts

Public
Alcon Laboratories

Rijksweg 14
Puurs B2870
BE
Scientific
Alcon Laboratories

Rijksweg 14
Puurs B2870
BE

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

1. Willing and able to attend all study visits
2. Must have all of the following in at least 1 eye at Screening (Day -15):
a. Meibomian Gland Dysfunction (MGD) grading for Expressibility * 2 and Meibum Quality * 2,
b. The average of 3 measures of TFBUT < 5 seconds, and
c. Unanesthetized Schirmer I test of * 3 mm
3. Must have an Ocular Surface Disease Index (OSDI) Score * 18 at Visit 1 (Day 0) prior to randomization (ie, after 2 weeks of run-in with Preservative-Free 0.9% Saline administered 4 times a day)
4. Must have best-corrected visual acuity of 55 letters or better in each eye as assessed using an ETDRS chart (letter read method)
5. Physician diagnosis of dry eye at least 6 months prior to Screening visit
6. Must be at least 18 years old and able to provide written informed consent

Exclusion criteria

1. Subjects on topical ocular treatments containing benzalkonium chloride (BAK), or other products with known toxicity to the corneal surface, within 30 days of Screening
2. Subjects who have started, stopped, or changed a lid hygiene regimen within 30 days of Screening. Note: Subjects who have been on a consistent lid hygiene regimen (ie, no change to the type of lid hygiene therapy that is being used as well as the frequency of use) for at least 30 days prior to Screening are not excluded. However, they cannot stop or change this regimen for the
duration of the study. In addition, subjects who do not currently use lid hygiene therapy cannot start for the duration of the study.
3. Use of any artificial tears/lubricants/gels/rewetting drops within 4 hours of Screening
4. Women of childbearing potential (those who are not surgically sterilized or postmenopausal for at least 2 years) are excluded from participating in this study if they

meet any of the following conditions:
* They are currently pregnant, or
* Test positive for pregnancy at Screening visit, or
* They are currently breast feeding, or
* Are not in agreement to use adequate birth control methods to prevent pregnancy throughout the study
5. Hypersensitivity to the use of any of the study products or allergy to any ingredient in the study products
6. Has an active ocular allergy
7. Ocular abnormalities that could adversely affect the safety or efficacy outcome such as:
* Eyelid anomalies that affect proper lid closure or proper blink function (eg, ectropion, entropion,
trichiasis, lid margin lesions, tarsal plate pathology, unresolved Bell*s palsy, etc.)
* Evidence of benign hemifacial spasm, benign essential blepharospasm, or eyelid apraxia
* Corneal disorders or abnormality such as active corneal ulcer, current corneal abrasion, keratoconus or corneal dystrophies which are actively changing or affect vision
* Metaplasia of the ocular surface
* History of corneal erosion syndrome or recurrent corneal erosion syndrome
* Clinically significant corneal epithelial anterior membrane dystrophy (subjects with minor/insignificant predominantly peripheral corneal epithelial dystrophy [not central dystrophy] without a history of corneal erosion syndrome can be included)
* Current filamentous keratitis
* Evidence of corneal neovascularization
* Any history of Herpes Simplex or Herpes Zoster Keratitis
8. Subjects taking any systemic medication known to cause dry eye (eg, anti-histamines, anti-depressants, antipsychotics, etc.) unless they have been on stable therapy/dosage for at least 30 days prior to Screening and will remain on a stable dosage for the duration of the study
9. Subjects with a history of any ocular or intraocular surgery (including periocular Botox injections), eyelid surgery, keratorefractive procedure, corneal transplant and its variants (eg, penetrating keratoplasty, DSEK, DMEK, DSAEK, DALK), or serious ocular trauma within 1 year of Screening
10. Active ocular infection (bacterial, viral or fungal), active inflammation not associated with dry eye such as uveitis, iritis, active blepharitis, active allergic conjunctivitis, etc
11. Subjects with punctal plug insertion or diathermy procedure initiated within 30 days of Screening
12. Have any significant illnesses that could, in the opinion of the Investigator, be expected to interfere with the study parameters
13. Subjects with active oculodermal rosacea with meibomian gland dysfunction
14. Have participated in an investigational drug or device trial within 30 days of Screening
15. Contact lens use within 30 days prior to Screening, or unwilling to avoid contact lens use during the course of the study
16. Unwilling to avoid the use of additional artificial tears/lubricants/gels/rewetting drops (other than the assigned study medication) throughout the course of the study (including the run-in period)

Study design

Design

Study phase:	4
Study type:	Interventional
Intervention model:	Other
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	07-04-2014
Enrollment:	48
Type:	Actual

Medical products/devices used

Generic name:	SYSTANE® BALANCE Lubricant Eye Drops
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	04-03-2014
Application type:	First submission
Review commission:	METC Amsterdam UMC

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
ClinicalTrials.gov	NCT01967147
CCMO	NL46716.018.13