protocol C-10-017: 'Lens Wearing Experience and Biocompatibility of a Marketed MPDS in Silicone Hydrogel and Soft Contact Lens Wearers'

Published: 03-02-2011
Last updated: 27-04-2024

The primary statistical objective of this study is to describe mean differences in corneal staining (type and area), for OPTI-FREE EverMoist Multi-Purpose Disinfecting Solution compared to baseline.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Vision disorders
Study type	Observational invasive

Summary

ID

NL-OMON36552

Source
ToetsingOnline

Brief title
Marketed MPDS in Contact Lens Wearers

Condition

- Vision disorders

Synonym
Lens Wearers

Research involving
Human

Sponsors and support

Primary sponsor: Alcon Laboratories

Source(s) of monetary or material Support: Alcon Laboratories

Intervention

Keyword: MPDS (Multi-Purpose Disinfecting Solution)

Outcome measures

Primary outcome

The Primary efficacy variable: corneal fluorescein staining (type and area)

Secondary outcome

Secondary variables:

- Likert Statements

- Contact Lens corrected Visual Acuity (Snellen)

- Average Lens Wearing Time

- Comfortable Lens Wearing Time

- Rewetting Drop Frequency

Study description

Background summary

The purpose of this study is to evaluate the effectiveness of a marketed multi-purpose solution for silicone hydrogel and soft contact lenses. Multi-purpose Solutions are used to clean, rinse, recondition, disinfect and store your contact lenses.

Study objective

The primary statistical objective of this study is to describe mean differences in corneal staining (type and area), for OPTI-FREE EverMoist Multi-Purpose Disinfecting Solution compared to baseline.

Study design

A single-arm, multicenter, not masked, not randomized trial with no control

group:
- OPTI-FREE EverMoist TM Multi-Purpose Disinfecting Solution

Number of centers: up to 8 in The Netherlands, Sweden and Australia
Number of patients: estimated 26 per center
Estimated Total Sample Size: 182 subjects

Duration of treatment: 30 days

Study burden and risks

You may experience side effects commonly associated with the use of contact lenses.
Most of them are listed below but they will vary from person to person:
- slight burning, stinging, or itching
- comfort less than when lens was first placed on the eye
- feeling of something in the eye (foreign body)
- excessive watering (tearing)
- unusual eye secretions
- redness of the eye
- reduced sharpness of vision (poor visual acuity)
- blurred vision
- rainbows or halos around objects
- sensitivity to light (photophobia)
- dry eyes

The possible benefit of taking part is a better tolerance of the contact lenses. Your participation, however, is contributing to scientific research information that may be used in the development of new, perhaps more successful, contact lens care products.

Contacts

Public
Alcon Laboratories

Rijksweg 14
2870 Puurs
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Scientific
Alcon Laboratories

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BE

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

1.Subjects must be 18 years of age and may be of any race and either gender
2.Subjects must wear silicone hydrogel or traditional soft contact lenses on a daily wear basis (minimum of 8 hours per day) for at least 1 month prior to Visit 1
3.Subjects must have habitually used a PHMB multi-purpose solution for at least 30 days prior to Visit 1
4.Subjects' vision must be correctable to 20/30 (Snellen) or better in each eye at distance with pre-study lenses at Visit 1
5. The IRB approved informed consent must be read, signed and dated by the subject or legally authorized representative before enrollment.
6.Subjects must be generally healthy and have normal ocular health and willing to follow the study procedures and visit schedule.
7. Subjects must be willing to follow the study procedures and visit schedule.

Exclusion criteria

1.Subjects who need to wear lenses on an extended wear basis during the study.
2.Subjects with a known sensitivity or intolerance to PHMB, POLYQUAD, or ALDOX preserved lens care products
3.Monocular subjects or subjects fit with only one lens
4.Subjects who have used additional lens care products other than a PHMB multi-purpose solution such as daily or enzyme cleaners within the one week prior to visit 1
5.Subjects must have discontinued the use of topical ocular over-the-counter (OTC) or prescribed topical ocular medications, with the exception of rewetting drops, within 7 days prior to visit 1
6.Any abnormal ocular condition observed during the visit 1 slit-lamp examination

7.Current or history of ocular infections or severe inflammation within 6 months prior to visit 1
8.current or history of blepharitis that required treatment within 6 months priot to visit 1
9.Conjunctival or structural lid abnormalities at visit 1
10.Abnormal corneal opacities or significant lenticular inclusions as observed with a slit-lamp at visit 1
11.Ocular surgery within 12 months prior to visit 1
12.Tarsal abnormalities within 6 months prior to visit 1
13.Use of any systemic medications, which have known or expected ocular or systemic side effects at visit 1, that in the clinical judgement of the investigator, could affect the subject's participation in this study unless they have been on a stable dosing regimen for a minimum of 30 days prior to visit 1.
14.Any systemic diseases at visit 1 that may affect the eye or be exacerabated by use of contact lenses or contact lens solutions or which could prevent subjects from wearing their lenses at least 8 hours per day
15.The investigator or his/her staff, family members of the investigator, family members of the investigator's staff, or individuals living in the households of these individuals
16.Participation in any clinical study within 30 days of visit 1
17.More than one member of the same household in this study.

Study design

Design

Study phase:	4
Study type:	Observational invasive
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	11-02-2011
Enrollment:	78
Type:	Actual

Ethics review

Approved WMO Date:	03-02-2011
Application type:	First submission
Review commission:	IRB Nijmegen: Independent Review Board Nijmegen (Wijchen)
Approved WMO Date:	16-02-2011
Application type:	Amendment
Review commission:	IRB Nijmegen: Independent Review Board Nijmegen (Wijchen)
Approved WMO Date:	23-02-2011
Application type:	Amendment
Review commission:	IRB Nijmegen: Independent Review Board Nijmegen (Wijchen)

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	NCT01252134
CCMO	NL34875.072.11