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Evaluation of two different eye drops in symptomatic soft contact lens wearers

Submission date
22/05/2019

Recruitment status
No longer recruiting

Registration date
07/06/2019

Overall study status
Completed

Last Edited
04/06/2019

Condition category
Eye Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
The aim of this study is to compare the performance of two artificial tear drops whilst wearing contact lenses. Both types of drop have been CE marked which means they are approved for use in the UK and are commercially available.

Who can participate?
People who currently wear contact lens correction and who are aged 18 years or older

What does the study involve?
The study comprises five scheduled visits across four to five separate days, covering a total duration of about one month. Participants wear their normal brand and prescription of contact lenses during the study. These are supplied free of charge for the month in which they are participating in the study. Participants also test two types of artificial tears, receiving one of the artificial tears for the first two weeks and the other artificial tears for the second two weeks. Both types of artificial tears are currently CE marked (i.e. approved for use in the European Union) and are tested to see how the artificial tears perform in comparison to each other across two weeks of use. All participants use both types of artificial tears, but the order in which they experience them is decided at random (like flipping a coin). Participants who normally use rewetting drops when wearing contact lenses need to stop using them for the duration of the days of the study.

What are the possible benefits and risks of participating?
The artificial tears are designed to make wearing contact lenses more comfortable, but there is no guarantee that this study will help. The artificial tears might not improve your comfort or your comfort might get worse. Information from this study may help researchers come up with new treatments to help others in the future. As the artificial tears are CE-marked, the risks from participating in this study are very low. All contact lens wear or lens care products, however, can carry a risk of serious injury to the eye. Participants should take particular care to follow the instructions from the investigator, especially if the study involves a different lens care regime to their normal one.

Where is the study run from?
VisionCare Research (UK)

When is the study starting and how long is it expected to run for?
May 2018 to April 2019

Who is funding the study?
CooperVision, Inc. (USA)

Who is the main contact?
Dr Nancy Keir
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

Protocol serial number
CV-18-28

Study information

Scientific Title
Crossover evaluation of two different eye drops in symptomatic soft contact lens wearers

Study objectives
The test eye drops will provide non-inferior subjective comfort and tear film stability compared to the control eye drops.

Ethics approval required
Old ethics approval format

Ethics approval(s)

Health Research Authority, North East - Newcastle & North Tyneside 1 Research Ethics Committee (NHSBT Newcastle Blood Donor Centre, Holland Drive, Newcastle upon Tyne, NE2 4NQ; Tel: +44(0)207 1048084; Email: nrescommittee.northeast-newcastleandnorthtyneside1@nhs.net), REC ref: 18/NE/0351

Primary study design
Interventional

Study design
Early feasibility randomised bilateral 4-week (2 x 2-week) cross over dispensing study

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Contact lens discomfort

Interventions
Symptomatic contact lens wearers will attend a screening, baseline visit then lens fit and follow-up visits for each 2 week part and there will be a minimum of 3 days between parts. In each part the subject will be fitted and issued with new (habitual brand) contact lenses in conjunction with either test or control drops before returning at 2 weeks for assessment. Subjects will be asked to respond to text questions at intervals for the duration of the study. Subjects will be randomised to the order of treatment (T/C or C/T). A random number generator (Microsoft Excel) will determine the randomisation of treatments to subjects, which is then incorporated into the Randomisation Log. To facilitate masking, the test products will be over-labelled and coded ‘A’ or ‘B’. Investigators will be masked to treatment product codes but not to the identity of the treatment products. Subjects will be masked to treatment product codes and the identity of the treatment products. The test eye drop is Clinitas Soothe Multi (Altacor) and the control eye drop is VisuXL (VISUfarma). Subjects will be requested to wear their contact lenses for at least 6 hours per day 5 days per week.
One drop from the over-labelled Test or Control product is to be applied to each eye according to the following insertion schedule.
Application 1: To the contact lens back surface upon removal from the storage case and just prior to insertion
Application 2: One drop to the lower fornix of each eye after 3 hours wear
Application 3: One drop to the lower fornix of each eye after 6 hours wear
Application 4: One drop to the lower fornix of each eye just after contact lens removal

Intervention Type
Other

Primary outcome(s)
Measured at baseline and after 2 weeks for each cross-over phase:
1. Binocular subjective comfort measured using a visual analogue scale, 1-100, in 1 unit steps
2. Treatment preference for comfort (1st/2nd) measured using Likert scale, 1-5
3. Pre-lens non-invasive break-up time (NIBUT) measured using a tearscope in seconds

Key secondary outcome(s)

Measured at baseline and after 2 weeks for each cross-over phase:
1. Average and comfortable wearing time, measured using verbal report (Hrs Mins)
2. Subjective dryness measured using visual analogue scale, 1-100, in 1 unit steps
3. Subjective vision quality overall measured using visual analogue scale, 1-100, in 1 unit steps
4. Limbal and bulbar hyperaemia (graded 0-4) measured using slit lamp biomicroscopy
5. Corneal staining by quadrant for type (graded 0-4 scale); area (0-10) measured using slit lamp biomicroscopy

Completion date
16/04/2019

Eligibility

Key inclusion criteria
Subjects will be defined as symptomatic contact lens wearers if they present with at least one of the following two criteria at baseline:
1. Difference in reported wearing time and comfortable wearing time >2 hours
2. Score ≥14 by CLDEQ-8

All subjects must satisfy the following conditions prior to enrolling in the study:
1. Be ≥18 years of age
2. Able to read, comprehend and sign an informed consent
3. Willing to comply with the wear and study assessment schedule
4. Adapted and current symptomatic soft CL wearers (i.e. >1 month of wear)
5. Spherical spectacle prescription between +6.00 and -10.00D (inclusive)
6. Correctable to 6/12 (20/40) or better in each eye
7. Require visual correction in both eyes (monovision and multifocal allowed but no monofit)
8. Have normal eyes with no evidence of any ocular abnormality or disease. For the purposes of this study a normal eye is defined as one having:
8.1. Clear central corneas
8.2. No anterior segment disorder
8.3. No amblyopia
8.4. No strabismus
8.5. No evidence of lid abnormality or infection
8.6. No conjunctival abnormality or infection that would contraindicate contact lens wear
8.7. No clinically significant slit lamp findings (i.e. corneal oedema, staining, central scarring, infiltrates, active neovascularisation)
8.8. No other active ocular disease or recent surgery

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

Key exclusion criteria
1. Previously shown sensitivity to any of the study solutions' components
2. Any systemic or ocular disease or allergies affecting ocular health
3. Using systemic or topical medications that will, in the investigator's opinion, affect ocular physiology or lens performance
4. Clinically significant (>Grade 3) corneal stromal oedema, corneal vascularisation, tarsal abnormalities, bulbar hyperaemia, limbal hyperaemia, or any other abnormality of the cornea that would contraindicate contact lens wear
5. Any corneal infiltrates or any corneal scarring or neovascularization within the central 5mm of the cornea
6. Keratoconus or other corneal irregularity
7. Aphakia or amblyopia
8. Diabetes
9. Known/reported infectious disease (e.g., hepatitis, tuberculosis) or an immunosuppressive disease (e.g., HIV)
10. History of chronic eye disease (e.g. Glaucoma or ARMD)
11. Pregnant or lactating or planning a pregnancy at the time of enrolment
12. Participation in any concurrent clinical trial or any clinical trial in the last 14 days

Date of first enrolment
09/11/2018

Date of final enrolment
01/03/2019

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Visioncare Research Clinic
Craven House
West Street
Farnham
United Kingdom
GU9 7EN

Sponsor information

Organisation
CooperVision, Inc.

Funder(s)

Funder type
Industry

Funder Name
CooperVision, Inc.

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are not expected to be made available. This is an early feasibility study conducted by CooperVision R&D in order to gain insights into product development. Data will be held at the Site (Visioncare) and a copy of the electronic database will be provided to the Sponsor (CooperVision).

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No