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Short-term evaluation of a commercial eyedrop in contact lens wearers (Part 2)

Submission date
21/02/2019

Recruitment status
No longer recruiting

Registration date
01/03/2019

Overall study status
Completed

Last Edited
08/03/2019

Condition category
Other

[ ] 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 purpose of this early feasibility study is to gain initial insights into the effects of an artificial tear drop whilst wearing contact lenses.

Who can participate?
Healthy, adapted contact lens wearers 18 years of age and older are eligible to participate.

What does the study involve?
This study involves wearing soft contact lenses and using commercial rewetting drops for approximately six hours per day, five days per week for a total of four weeks. During this time you will be asked to attend 5 study visits on 4 to 5 separate days. The measurements taken throughout this study will be no different to those that should be conducted at a normal contact lens check-up visit.

What are the possible benefits and risks of participating?
There might not be direct benefits to the participants in this study. However, participation may contribute to scientific research information that may be used in the development of new contact lens products. The risks to participants in this study are similar to those associated with normal daily wear of soft contact lenses.

Where is the study run from?
This study will be run at one site: Visioncare Research Clinic in Farnham, United Kingdom.

When is the study starting and how long is it expected to run for?
The study is planned to start in July 2017 and is expected to run for approximately 3 months.

Who is funding the study?
The study is funded by CooperVision, Inc.

Who is the main contact?
Nancy Keir, nkeir@coopervision.com

Contact information

Type(s)
Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
N/A

ClinicalTrials.gov (NCT)
N/A

Protocol serial number
CV-17-07

Study information

Scientific Title
Crossover evaluation of Clinitas Soothe eye drops in symptomatic soft contact lens wearers (Part 2)

Acronym
N/A

Study objectives
The test product will provide non-inferior subjective comfort and pre-lens tear stability compared to a control product.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 07/04/2017, North West - Liverpool East Research Ethics Committee (Barlow House, 3rd Floor, 4 Minshull Street, Manchester, M1 3DZ; 02071048127), ref: 17/NW/0196.

Study design

Single site, bilateral, randomised, 2-week cross-over dispensing study
Participants will be randomised to the order of study product. Investigators and subjects will not be masked to the study product.

Primary study design
Interventional

Study type(s)
Other

Health condition(s) or problem(s) studied
N/A

Interventions
Habitual soft contact lenses will be worn and rewetting drops applied each day for a total of approximately four weeks. Two types of rewetting drops will be tested and participants will receive one of the rewetting drops to be used for the first two weeks and the other rewetting drop for the second two weeks, with a minimum of 3 days in between. Both types of rewetting drops are currently CE marked (i.e. approved for use in the European Union). All participants who agree to participate in this study will experience both types of rewetting drops, but the order in which they experience them will be decided at random (like flipping a coin).

Intervention Type
Device

Primary outcome(s)
Measured at each of the 4 assessment visits:
1. Subjective comfort [1-100, in 1 unit steps] will be measured using a Visual Analog Scale.
2. Average comfortable wearing time [Hrs:Mins] will be recorded by subjects.
3. Pre-lens Non-invasive break-up time (NIBUT) [s] will be measured using a Keeler Tearscope.

Key secondary outcome(s))
Measured at each of the 4 assessment visits:
1. Subjective dryness [1-100, in 1 unit steps] will be measured using a Visual Analog Scale.
2. Subjective vision quality overall [1-100, in 1 unit steps] will be measured using a Visual Analog Scale.
3. Treatment preference for comfort(1ST/2ND) [LIKERT 1-5] will be measured using a Likert Scale.
4. Ocular health (limbal hyperaemia and corneal staining) will be measured using a slit lamp microscope.

Completion date
17/10/2017

Eligibility

Key inclusion criteria
1. ≥18 years of age
2. Adapted and current symptomatic soft CL wearers (i.e. >1 month of wear)

3. Spherical spectacle prescription between +6.00 and -10.00D (inclusive)
4. Correctable to 6/12 (20/40) or better in each eye
5. Require visual correction in both eyes (monovision and multifocal allowed but no monofit)
6. Have normal eyes with no evidence of any ocular abnormality or disease.

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 edema, corneal vascularisation, tarsal abnormalities, bulbar hyperemia, limbal hyperemia, 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. Has 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 a concurrent clinical trial or any clinical trial (other than CDRP-402 Part 1) in the last 14 days

Date of first enrolment
28/06/2017

Date of final enrolment
01/08/2017

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. (USA)

Funder(s)

Funder type
Industry

Funder Name
CooperVision, Inc.

Results and Publications

Individual participant data (IPD) sharing plan
There are no plans for publication or to make the dataset available.

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
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes