ISRCTN11194798 https://doi.org/10.1186/ISRCTN11194798

Short-term evaluation of a commercial eyedrop in contact lens wearers

Submission date	Recruitment status	[ ] Prospectively registered
20/02/2019	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
01/03/2019	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
08/03/2019	Other	[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
This is an early feasibility study to gain preliminary insights into the retention time of a commercial eyedrop in contact lens wearers.

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

What does the study involve?
Following a screening appointment to confirm eligibility, all eligible study participants will be asked to instill two different commercial eye drops with their contact lenses using three different regimens (i.e. one to four times per day at different time points during the day), on three different days. Each study day will be separated by a minimum of 1 day and a maximum of 10 days.

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 June 2017 and is expected to run for approximately 2 months.

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

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

Study website
N/A

Contact information

Type(s)
Scientific

Contact name
Dr Nancy Keir

Contact details
5870 Stoneridge Dr, Suite 1
Pleasanton
United States of America
94588
925-730-6768
nkeir@coopervision.com

Additional identifiers

EudraCT/CTIS number
N/A

IRAS number

ClinicalTrials.gov number
N/A

Secondary identifying numbers
CV-16-58

Study information

Scientific Title
Crossover evaluation of Clinitas Soothe® eye drops in symptomatic soft contact lens wearers (part 1)

Acronym
N/A

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

Ethics approval required
Old ethics approval format

Ethics approval(s)

Approved 12/06/2017, North East - Newcastle & North Tyneside 1 Research Ethics Committee (Jarrow Business Centre, Rolling Mill Road, Jarrow, NE32 3DT; 0207 104 8117), ref: 17/NE/0094.

Study design
Single site, 3-day, contralateral, randomised, single-masked, early feasibility study.
The order of the study products will be determined randomly.

Primary study design
Interventional

Secondary study design
Randomised cross over trial

Study setting(s)
Other

Study type(s)
Other

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet

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

Interventions
This was a feasibility study to evaluate the retention time of a polymer on the eye in order to provide insights into new product development programs. Each commercial eyedrop was used by all subjects according to three different regimens/schedules. The regimens/schedules were assigned randomly over three study days. Each study day was separated by a minimum of 1 day and a maximum of 10 days.

Intervention Type
Device

Primary outcome measure
Measured on each study day:
1. Monocular comfort [1-100, in 1 unit steps] will be measured using a Visual Analog Scale.
2. Pre-lens Non-invasive break-up time (NIBUT) [s] will be measured using a Keeler Tearscope.

Secondary outcome measures
Measured on each study day:
1. Subjective dryness [1-100, in 1 unit steps] will be measured using a Visual Analog Scale.
2. Subjective vision quality [1-100, in 1 unit steps] will be measured using a Visual Analog Scale.
3. Lens preference for comfort [R/L, 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.

Overall study start date
15/02/2017

Completion date
07/08/2017

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 allowed but no monofit)
6. Have normal eyes with no evidence of any ocular abnormality or disease.

Participant type(s)
Healthy volunteer

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
10-15

Total final enrolment
15

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 any concurrent clinical trial or in last 14 days.

Date of first enrolment
16/06/2017

Date of final enrolment
01/07/2017

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Visioncare
Craven House, Arundell Place, West Street
Farnham
United Kingdom
GU9 7EN

Sponsor information

Organisation
CooperVision Inc. (USA)

Sponsor details
5870 Stoneridge Drive
Pleasanton
United States of America
94588
925-730-6768
nkeir@coopervision.com

Sponsor type
Other

Website
http://coopervision.com

Funder(s)

Funder type
Industry

Funder Name
CooperVision, Inc.

Results and Publications

Publication and dissemination plan
No publication is intended for this early feasibility trial.

Intention to publish date

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