ISRCTN26121992 https://doi.org/10.1186/ISRCTN26121992

Effect of sodium hyaluronate eyedrop on contact lens wettability

Submission date
20/11/2017

Recruitment status
No longer recruiting

Registration date
30/11/2017

Overall study status
Completed

Last Edited
19/01/2018

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
Sodium hyaluronate (hyaluronate acid [HA]) eyedrops are used extensively in patients complaining of dry eye, including contact lens wearers. The aim of this study is to compare the effect of cross-linked HA to non-cross linked HA eyedrops on the tear film of contact lens wearers.

Who can participate?
Adults aged 18 and over who have healthy eyes and are currently wearing daily disposable contact lenses with discomfort/dry eye symptoms

What does the study involve?
The potential participants attend the clinic for Visit 1 to obtain their informed consent and evaluate their suitability to take part in the study. The potential participants are asked to come wearing their usual contact lenses that day. If the potential participant consents to taking part, measurements of visual acuity and ocular (eye) integrity are taken. If they fulfill the criteria for the study, they are scheduled to attend the test visits 2 and 3 (two to seven days later). Participants return for their two test visits having worn their usual contact lenses around six hours that day. During the test visits, a single drop of the first study eyedrop (randomly chosen) is instilled in each eye. Tests are performed before the eyedrop instillation, at multiple time points over a 3-hour period after eyedrop instillation and after lens removal. Tests include video recording of the tear film in one eye only and completion of questionnaires. At the end of each test visit, the participants' eyes are examined for ocular integrity. Visit 3 follows the same routine as Visit 2, except that the eyedrop used is the eyedrop not used in Visit 2.

What are the possible benefits and risks of participating?
Participants may not directly benefit from taking part in this study but have the opportunity to try different eyedrops to manage their symptoms while wearing contact lenses. Both study eyedrops are CE marked eyedrops. The examination and assessments of the front part of the eye are at no cost to participants and can be considered beneficial by documenting their current health status. All participants are current daily disposable soft contact lens wearers and wear their own contact lenses. The risks of taking part in the study are no greater than those associated with wearing their own contact lenses. All the tests are routine clinical procedures or

specialized procedures and none present any increased risk to participants compared with normal clinical routine.

Where is the study run from?
Ocular Technology Group - International (UK)

When is the study starting and how long is it expected to run for?
November 2017 to January 2018

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

Who is the main contact?
Ms Trisha Patel

Contact information

Type(s)
Public

Contact name
Ms Trisha Patel

Contact details
66 Buckingham Gate
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SW1E 6AU

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
CV 17-62

Study information

Scientific Title
Effect of sodium hyaluronate eyedrop on contact lens wettability

Study objectives
Despite having a new contact lens every day, a significant percentage of daily disposable contact lens wearers are still having discomfort/dryness (symptoms) towards the end of the day. Use of eyedrops may be beneficial and selecting the most appropriate formulation within a category of eyedrops will be important for long term success. The rationale for the study is that the sodium

hyaluronate (HA) eyedrop formulation that achieves the best effect following a single instillation is likely to have the best long-term efficacy when managing symptomatic contact lens wearers. The purpose of the study will be to quantify the effect of cross-linked HA (test) compared to non-cross linked HA (control) on contact lens on eye wettability by evaluating the tear film characteristics in symptomatic lens wearers.

Hypothesis: cross-linked HA eyedrop produces a greater improvement than non-cross-linked HA eyedrop in tear film characteristics and the duration for the improvement.

Ethics approval required
Old ethics approval format

Ethics approval(s)
North West - Liverpool Central Research Ethics Committee, 15/11/2017, ref: 17/NW/0659

Study design
Single-centre interventional single-arm double-masked (investigator and participant) randomized order (control and test) cross-over bilateral prospective study

Primary study design
Interventional

Secondary study design
Randomised cross over trial

Study setting(s)
Other

Study type(s)
Treatment

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
Dry eyes, eyedrops, contact lens symptomatology, tear film

Interventions
The potential participants will attend the clinic for Visit 1 to obtain their informed consent and evaluate their suitability to take part in the investigation. The potential participants will be asked to come wearing their habitual contact lenses that day. If the potential participant consents to taking part, measurements for visual acuity and ocular integrity will be taken. If they fulfill the inclusion and exclusion criteria, they will be enrolled and scheduled to attend the test visit 2 and 3 (two to seven days later). Participants will return for their two test visits having worn their habitual contact lenses around six hours that day. Participants will use the cross-linked HA (test) and non-cross linked HA (control) eyedrops in a randomized order. During the test visits, a single drop of the first study eyedrop (randomly assigned and masked) will be instilled in each eye in the clinic (in office use only) by unmasked study staff. Evaluations will be performed prior to the eyedrop instillation, at multiple time points over a 3-hour period after eyedrop instillation and after lens removal. Evaluations include tear film digital non-invasive

video recording using the slit-lamp tearscope illumination in one eye only and completion of subjective questionnaires. At the end of each test visit, the participants' eyes will be examined with a slit lamp biomicroscope for ocular integrity. Visit 3 will follow the same routine as Visit 2, except that the eyedrop used will be the eyedrop not used in Visit 2. Participants' eyes will be examined by the investigator before they leave the clinic and are discharged from the study at the end of Visit 3.

Intervention Type
Supplement

Primary outcome measure
Measured using Tearscope at study visit 2 and 3 at pre-instillation of eyedrop and 5, 30, 60, 90, 120 and 180 minutes post instillation:
1. Tear film non-invasive break-up time
2. Contact lens surface exposed area at blink
3. Contact lens surface tear film protective index

Secondary outcome measures
Measured at study visit 2 and 3 at pre-instillation of eyedrop and 5, 30, 60, 90, 120 and 180 minutes post instillation and prior to contact lens removal:
1. Subjective comfort, rated using 0-100 point Visual Analog Scale (VAS)
2. Subjective vision, rated using 0-100 point Visual Analog Scale (VAS)

Overall study start date
16/11/2017

Completion date
31/01/2018

Eligibility

Key inclusion criteria
1. At least 18 years old
2. Have read and understood the Participant Information Sheet
3. Have read, signed and dated the Informed Consent
4. Current symptomatic daily disposable contact lens wearer
5. Spectacle refraction: distance sphere: -6.00D to + 4.00D; Astigmatism: 0.00D to -0.75D
6. Best corrected visual acuity of at least 20/30 in each eye
7. Have normal eyes with the exception of the need for visual correction
8. Be willing and able to adhere to the instructions set in the clinical protocol and maintain the appointment schedule

Participant type(s)
Healthy volunteer

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
A total of 20 participants will be enrolled

Key exclusion criteria
1. Ocular anterior segment infection, inflammation, abnormality, or active disease that would contraindicate contact lens wear
2. Use of systemic or ocular medications for which contact lens wear could be contraindicated as determined by the investigator
3. Monocular participants (only one eye with functional vision) or participants fit with only one contact lens
4. Any moderate or severe ocular condition observed during the slit-lamp examination at the enrolment visit
5. History of herpetic keratitis, ocular surgery or irregular cornea
6. Known pregnancy or lactation during the study period
7. Enrollment of 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
8. Participation in any clinical trial within 30 days of the enrolment visit

Date of first enrolment
17/11/2017

Date of final enrolment
31/12/2017

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Ocular Technology Group - International
66 Buckingham Gate
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SW1E 6AU

Sponsor information

Organisation
CooperVision Inc. (USA)

Sponsor details
5870 Stoneridge Drive
Suite 1
Pleasanton
United States of America
94588

Sponsor type
Industry

Funder(s)

Funder type
Industry

Funder Name
CooperVision, Inc.

Results and Publications

Publication and dissemination plan
The protocol has not been published and is not available online. Publication of the results will depend upon the sponsor's decision.

Intention to publish date
30/06/2019

Individual participant data (IPD) sharing plan
The data sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

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