

Effect of sodium hyaluronate eyedrop on contact lens wettability

Submission date 20/11/2017	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 30/11/2017	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 19/01/2018	Condition category Eye Diseases	<input type="checkbox"/> Individual participant data <input type="checkbox"/> 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

London

United Kingdom

SW1E 6AU

Additional identifiers

Protocol serial number

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

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s)

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)

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

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

United Kingdom

England

Study participating centre

Ocular Technology Group - International

66 Buckingham Gate

London

United Kingdom

SW1E 6AU

Sponsor information

Organisation

CooperVision Inc. (USA)

Funder(s)

Funder type

Industry

Funder Name

CooperVision, Inc.

Results and Publications

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