ISRCTN17565450 https://doi.org/10.1186/ISRCTN17565450

Analysis of the tear components taken up by contact lenses

Submission date	Recruitment status	[ ] Prospectively registered
18/09/2017	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
06/10/2017	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
06/09/2019	Eye Diseases	[ ] Record updated in last year

Plain English summary of protocol

Background and study aims

Dry eyes is a common condition that occurs when the eyes don't make enough tears or the tears evaporate too quickly,
leading to the eyes drying out and becoming red, swollen and irritated. It can be caused by wearing contact lenses. There are differences between contact lens wearers with and without dry eyes in the various tear components taken up by contact lenses. The difference can be detected after a single day of wear.The aim of this study is to collect contact lenses worn by wearers who have dryness symptoms versus those with no symptoms under controlled conditions for a period of 8 hours for analysis of tear components taken up by the contact lenses.

Who can participate?

Adults who are at least 18 and who have healthy eyes and currently wearing contact lenses

What does the study involve?

Participants' eyes are examined by the investigator and video recording and assessment of their tears is performed. At the next visit (1 to 27 days after the first visit), they are given a pair of commercially available study contact lenses to be worn for 8 hours that day. They are asked to complete a short contact lens symptom questionnaire after 2, 4, 6 and 8 hours of wear. At the end of the 8 hours contact lens wear, the study contact lenses are removed by the study staff and stored for analysis. The investigator assesses the health of their eyes and checks their vision. All participants undergo the same routine.

What are the possible benefits and risks of participating?

Participants may not directly benefit from taking part in this study. 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 contact lenses have the potential of causing injury to the eye. Since they are wearing commercially available contact lenses for 8 hours at the clinic, the risks of participating in this study are considered to be similar to those of their normal contact lens wear.

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?
September 2017 to December 2017

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
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SW1E 6AU

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
CV 17-32

Study information

Scientific Title
Tear component uptake by contact lenses: symptomatic vs asymptomatic wearers

Study objectives
The hypothesis will be that symptomatic and asymptomatic contact lens wearers will exhibit differences in their tear film properties.

Ethics approval required
Old ethics approval format

Ethics approval(s)
National Research Ethics Committee - South West - Exeter, 13/09/2017, ref: 17/SW/0160

Study design
Single-arm open-label bilateral prospective study with investigator masking

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Other

Study type(s)
Screening

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

Health condition(s) or problem(s) studied
Dry eyes, tear film

Interventions
The etiology of contact lens dry eye has been traditionally reported to be due to excessive evaporation associated with an abnormal lipid layer, however, recent work indicates that the problem is more complex. In this study a further aspect of interest will be to identify the type of anomaly associated with the symptomatology. The study population will comprise of 50 participants: symptomatic (test group) 25 participants and asymptomatic (control group): 25 participants. The two groups will be matched for gender (12 males and 13 females in each group) because of the potential for difference in symptomatology with gender. Baseline pre-corneal tear film, tear prism digital video recording and tear film evaporimetry will be performed. All participants will wear the same type of study contact lenses under controlled conditions in the clinic for a period of 8 hours. They will be asked to complete the contact lens symptomatology questionnaire after 2, 4, 6 and 8 hours of wear. Worn contact lenses will be collected at the end of wear, stored and analyzed. Their eyes will be examined by the investigator before they are discharged from the study.

Intervention Type
Other

Primary outcome measure
1. Subjective comfort, rated using a 100-point Visual Analog Scale (VAS) after 2, 4, 6 and 8 hours of wear
2. Tear film components, analysed from worn contact lenses at the end of the day

Secondary outcome measures
Contact lens tear film biophysical properties (pre-corneal tear film, tear prism digital video recording and tear film evaporimetry) measured at baseline visit

Overall study start date
13/09/2017

Completion date
31/12/2017

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 spherical daily 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. Symptomatic wearers (test group):
7.1. At least three hours difference between daily wearing time and comfortable wearing time
7.2. Classified as symptomatic as per study criteria
8. Asymptomatic wearers (control group):
8.1. At most two hours difference between daily wearing time and comfortable wearing time
8.2. Classified as asymptomatic as per study criteria
9. Have normal eyes with the exception of the need for visual correction
10. 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 50 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 contraindicates as determined by the investigator
3. Monocular participants (only one eye with functional vision) or participants fit with only one 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. Enrolment 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
14/09/2017

Date of final enrolment
30/11/2017

Locations

Countries of recruitment
England

United Kingdom

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

Sponsor information

Organisation
CooperVision Inc. (USA)

Sponsor details
5870 Stoneridge Drive
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
31/01/2019

Individual participant data (IPD) sharing plan
All of the individual participant study data collected during the trial for all the required study variables (incl. tear film videos/photos) listed in the protocol will be stored in the OTGi server located at 66 Buckingham Gate, London. Participants are referred to by participant number and not name; however, initials and date of birth will be recorded on the study documents. A dedicated server is used and the hardware is firewalled and is protected by antivirus software. The database is backed up daily and encrypted onto an external device. This encrypted data is then mirrored remotely to an external offsite location. Participants are advised that their data are being collected for research purposes and may be used for additional scientific research, educational purposes and publications. Information will be encoded in order to safeguard their confidentiality, and if the results of the research are used in reports of the study or for any presentations, their identity will remain confidential. Any study information which is transferred to the sponsor will be fully anonymised and neither the participant's identity or date of birth will be transferred; they will only be referred to by their participant number. Participants are provided with all of the information relating to their confidentiality and how their data may be used in the Participant Information Sheet and provide written consent for this.

IPD sharing plan summary
Stored in repository

Study outputs

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