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Evaluation of Rexon-Eye efficacy for dry eye subjects

Submission date	Recruitment status	[_] Prospectively registered
23/02/2018	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
23/03/2018	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
15/04/2020	Eye Diseases	

Plain English summary of protocol

Background and study aims
Dry eye is a common condition that occurs when the eyes don't make enough tears (aqueous deficient), or the tears evaporate too quickly (evaporative), leading to the eyes drying out and becoming red, swollen and irritated. A number of instruments have been developed to offer in-office dry eye treatment, and can also be used to treat contact lens discomfort. The Rexon-Eye device is intended to treat both evaporative and aqueous deficient dry eyes. The device produces low power, high frequency current delivered through an eye mask over closed eyes to increase cellular regeneration and reactivate the tear system. The aim of this study is to measure the effect of using the Rexon-Eye device for dry eye treatment on contact lens wearers with dry eye symptoms and dry eye sufferers who do not wear contact lenses.

Who can participate?
Adults who are at least 18 and who have healthy eyes and are currently wearing daily disposable contact lenses with discomfort/dry eye symptoms, and dry eye sufferers who do not wear contact lenses

What does the study involve?
Participants are randomly allocated to either the test group receiving the standard Rexon-Eye treatment or the control group receiving the placebo (dummy) treatment.The study involves six visits over a four-month period: at the start of the study, four weekly 20-minute treatment sessions with the device, and a 3-month follow-up visit. Throughout the study, the daily disposable contact lens wearers wear their usual contact lenses following their regular routine, and the non-contact lens wearers use their usual spectacles or no correction and continue to use their usual eyedrops. The participants are asked to complete a few simple questionnaires relating to dry eyes, comfort and vision. Digital photographs of their eyes and tear film video are taken. The treatment is given at the study site only. At the end of each study visit, the participants' eyes are examined.

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 a new CE marked device for the treatment of dry eye. 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. The risks of taking part in the study are no greater than those associated with wearing their own contact lenses. Rexon-Eye treatment is non-invasive. Participants wear an eye mask covered with an internal, disposable, sterile cloth to avoid direct contact of the mask with their skin. The eyes are closed during the treatment. All the assessments 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?
February 2018 to October 2018

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

Who is the main contact?
Trisha Patel

Contact information

Type(s)
Public

Contact name
Ms Trisha Patel

Contact details
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66 Buckingham Gate
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United Kingdom
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Additional identifiers

Protocol serial number
CV 18-03

Study information

Scientific Title
Evaluation of Rexon-Eye efficacy in symptomatic contact lens wearers and dry eye sufferers

Study objectives
The hypothesis will be that Rexon-Eye treatment decreases symptomatology, ocular tissue anomalies and increases tear volume.

The rationale for the study is that symptomatic contact lens wearers with ocular tissue and/or tear film anomalies should benefit in a similar manner from Rexon-Eye treatment as dry eye

sufferers. The use of the technology is particularly interesting in symptomatic contact lens wearers for whom ocular tissue anomalies (staining) are observed, indicating abnormal goblet cells, and/or low tear volume are recorded, indicating lacrimal gland deficiency. Therefore, the rationale being to fully test the efficacy and potential application of Rexon- Eye, both symptomatic contact lens wearers and dry eye sufferers will be enrolled in the study.

Ethics approval required
Old ethics approval format

Ethics approval(s)
South West - Exeter Research Ethics Committee, 14/02/2018, ref: 18/SW/0026

Primary study design
Interventional

Study design
Non-dispensing double-masked randomized bilateral parallel-group study

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Dry eye

Interventions
Participants are randomly assigned to either the test group receiving the standard Rexon-Eye treatment or the control group receiving the placebo treatment in a 2:1 ratio. The study will involve six study visits (baseline/enrollment, four weekly in-office treatment sessions and a follow up visit at 3 months).

Throughout the study, the daily disposable contact lens wearers will wear their usual contact lenses following their regular routine, and the non-contact lens wearers will use their habitual vision correction (spectacles) or no correction and will continue to use their habitual eyedrops. The participants will be asked to complete a few simple questionnaires relating to dry eyes, comfort and vision. Digital photographs of their eyes and tear film video will be taken. The treatment will be administered at the study site only. At the end of each study visit the participants' eyes will be examined for ocular integrity and visual acuity. They will be discharged from the study at the end of Visit 6.

Intervention Type
Device

Primary outcome(s)
1. Symptomatology for contact lens wearers is measured using the CLDEQ-8 score at all visits (baseline/enrollment, four weekly in-office treatment sessions and a follow up visit at 3 months)
2. Symptomatology for non-contact lens wearers is measured using OSDI score at at all visits (baseline/enrollment, four weekly in-office treatment sessions and a follow up visit at 3 months)
3. Ocular tissue is measured using bulbar conjunctival staining in mm2 at baseline, 1 month and 3 months
4. Tear volume is measured using tearscope by evaluation of tear prism surface area at eye opening and at blink in mm at baseline, 1 month and 3 months

Key secondary outcome(s)
1. Tear film non-invasive break-up time in seconds is measured using tearscope at baseline, 1 month and 3 months
2. Contact lens or ocular surface exposed area at the time of the blink (as applicable) is measured using tearscope at baseline, 1 month and 3 months
3. Contact lens or ocular surface tear film protective index (as applicable), measured using tearscope at baseline, 1 month and 3 months

Completion date
31/10/2018

Eligibility

Key inclusion criteria
Group 1: current daily disposable contact lens wearers
1. Age 18 to 45 years
2. Symptomatic wearers defined by a CLDEQ-8 score ≥ 14
3. Presence of ocular tissue anomaly and/or low tear volume:
Group A: ocular tissue anomalies defined as bulbar conjunctival lissamine green staining Grade 2 or greater and/or
Group B: tear volume in the lower population quartile for contact lens wearers
4. Spectacle refraction: Sphere: -6.00D to + 4.00D, Astigmatism: 0.00D to -0.75D
5. Best corrected visual acuity of at least 20/30 in each eye
6. Have normal eyes with the exception of the need for visual correction
7. Be willing and able to adhere to the instructions set in the clinical protocol and maintain the appointment schedule

Group 2: non-contact lens wearers dry eye sufferers
1. Age 18 to 65 years
2. Symptomatic dry eye sufferer defined by an OSDI score ≥ 13
3. Presence of ocular tissue anomaly and/or low tear volume:
Group A: ocular tissue anomalies defined as bulbar conjunctival lissamine green staining Grade 2 or greater and/or
Group B: tear volume in the lower population quartile for non-contact lens wearers
4. Spectacle refraction: Sphere: -6.00D to + 4.00D, Astigmatism: 0.00D to -2.50D
5. Best corrected visual acuity of at least 20/30 in each eye
6. Have normal eyes with the exception of the need for visual correction
7. 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. Use of ocular medications
4 Monocular participants (only one eye with functional vision) or participants fit with only one contact lens
5. Any moderate or severe ocular condition observed during the slit-lamp examination at the enrolment visit
6. History of herpetic keratitis, ocular surgery or irregular cornea
7. Known pregnancy or lactation during the study period
8. 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
9. Participation in any clinical trial within 30 days of the enrolment visit

Date of first enrolment
12/03/2018

Date of final enrolment
25/06/2018

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. (USA)

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?
Basic results		14/12/2018	15/04/2020	No	No
HRA research summary			28/06/2023	No	No