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Investigation of eye response to two different contact lens solutions

Submission date	Recruitment status	[_] Prospectively registered
20/03/2019	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
21/03/2019	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
21/05/2021	Eye Diseases	

Plain English summary of protocol

Background and study aims
The literature currently indicates that soft contact lens wear may stimulate the inflammatory response of the ocular surface. Our previous study has shown that re-usable lenses stimulate a higher inflammatory response to the ocular surface as compared to a daily disposable lens. However, no difference was found between the two types (materials) of the re-usable lenses investigated. We postulate that the contact lens solutions used for lens cleaning and storing could be one of the factors that triggers an inflammatory response. Therefore, by using two clinical examinations, in vivo confocal microscopy and impression cytology, as employed in the previous study, we would like to further investigate the inflammatory response of the two types of solution with two types of soft contact lens material.

This work aims to investigate if a low-grade inflammatory response of the ocular surface takes place during normal contact lens wear when used with two different types of care solution. The contact lenses and care solutions are all CE-marked, which means they are approved for sale in the European union. Additionally, the relationship between the lenses and comfort will be investigated. The worn lenses used in this study will be collected to measure the protein deposited. The results from this work may help us to understand more fully the effect of a contact lens material and care solutions on-eye and aid in the future development of contact lenses.

Who can participate?
We require 15 volunteers for this work who are current soft contact lens wearers. Volunteers should also be in possession of a wearable pair of spectacles. People with some eye or health problems are unable to participate: those with systemic, infectious and immunosuppressive disease, those currently using anti-inflammatory or pain medication, those currently using any topical medication, those who have had any previous eye surgery, and women who are pregnant or breast-feeding.

What does the study involve?
At the first study visit (Dispensing visit), the Optometrist investigator will examine your eyes and a low powered lens will be fitted to both eyes. You will be required to wear your own spectacles over the lenses. Over the six weeks study period, you will wear two lens types each for a one

week period. You will also be required to wear your spectacles for four one-week periods. These are wash-out periods and you will be asked to wear your own spectacles i.e. not to wear any contact lenses at all. Two main examinations to assess the ocular surface will be carried out at the follow- up visits: in vivo confocal microscopy and impression cytology.

What are the possible benefits and risks of participating?
The overall results might not benefit you directly, but they will contribute towards the development of better contact lenses. There are risks to using contact lenses (and related products) and as such, there are risks of participating in this study. It is possible that the following may occur: pain, abrasion of the eye, the sensations of itching, burning or stinging, excessive tear production, unusual secretions, redness, reduced sharpness of vision, blurred vision, sensitivity to light or dry eyes. In rare instances, corneal ulcers, scarring, the growth of blood vessels into the cornea, temporary or permanent decreased vision, iritis or infections of the eye might occur. Further treatment may be required and you may also be precluded from future contact lens wear.

Where is the study run from?
This study was set up by Eurolens Research at the University of Manchester.

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

Who is funding the study?
The Government of Malaysia

Who is the main contact?
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Contact information

Type(s)
Public

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
ER17-622

Study information

Scientific Title
An investigation of the ocular inflammatory response for two soft contact lens solutions

Study objectives
To investigate the inflammatory response of the ocular surface when using two contact lens solutions with two soft contact lenses with different materials. Furthermore, to study the deposits composition onto and within the lenses, and to investigate if the inflammatory response is associated with comfort.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 09/11/2017, University Research Ethics Committee (4) (The University of Manchester, Oxford Rd, Manchester, M13 9PL; 0161 275 2167; clinicaltrials@manchester.ac.uk), ref: 2017-2655-4096.

Study design
Randomised subject-masked single-centre trial and crossover study

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
Subclinical inflammation of the ocular surface

Interventions
Fifteen soft contact lens wearers were recruited and instructed to wear two different types of soft contact lens and no lens wear (control) for one week, with a one week washout period in between each lens/no lens wear period. The order of study lenses wear/no lens wear were randomised. All lenses (very low power) were worn in both eyes on a daily wear basis and subjects were required to wear their own spectacles on top of the study lenses. Subjects were also required to wear their spectacles only during the washout periods.

The study lenses were:
1) Acuvue 2.
2) Acuvue Oasys with Hydraclear Plus.

The study care solutions were:
1) Oxysept 1 Step: used for the right lens.
2) Opti-Free Replenish: used for the left lens.

Subjects were required to attend four visits – a dispensing visit followed by three follow- up visits. During the dispensing visit, preliminary eye examinations including visual acuity, refraction and slit lamp biomicroscopy were carried out. Subjects were then fitted with one of the study lenses and comfort score was measured using visual analogue scale (0-100). The care solutions were given and instructions oh how to clean and store the lenses were provided. Unless the subjects were randomised for the control period, no care solution provided. All subjects were asked to at least wear the lenses eight hours per day, 6 days per week.

At the follow-up visits, any medical or ocular issues related to lens worn was recorded. Comfort score was measured separately (left and right eye). The lenses were then removed and transferred into separate bijou tubes and kept in the -80 freezer. Two main investigative examinations, in vivo confocal microscopy and conjunctival impression cytology were carried out under topical anaesthesia, Oxybuprocaine hydrochloride 0.4%. A complete slit lamp biomicroscopy and visual acuity examinations were then carried out.

If a lens type was randomised to the next study period (the week after the one week washout), the lenses were then applied to ensure the fitting was adequate. the lenses were then removed and discarded. New sealed pairs of the same lens were given to the subject. Subjects were reminded to start wearing the lenses after the one week washout period. All subjects were asked to at least wear the lenses eight hours per day, 6 days per week, together with their spectacles on top of the study lenses.

The participants were randomised using an online research randomiser (https://www.randomizer.org). The follow-up visits were carried out after one week (7 days) of wearing each of the study lens-solution combination.

Intervention Type
Other

Primary outcome measure

1. In vivo confocal microscopy: The density of presumed dendritic cells in the cornea, bulbar and upper and lower eyelid margin of the conjunctiva were calculated using a semi-automated software (CCMetrics, M.A.Dabbah, ISBE, The University of Manchester, UK). Additionally, the presence of white spots (presumably leukocytes) in the upper and lower eyelid margin areas was also quantified using the same software.
2. Impression cytology: Each impression sample were stained with antibody markers, CD45 (leukocyte common antigen), CD3 (T cells) and CD11c (dendritic cells) (BioLegend, UK) and analysed using flow cytometry.

Tests carried out at baseline and after one week (7 days) of wearing each of the study lens-solution combination.

Secondary outcome measures
Association between the subclinical inflammation parameters and ocular comfort at each follow-up visit was statistically analysed.

Overall study start date
10/11/2017

Completion date
31/01/2018

Eligibility

Key inclusion criteria
1. Legal age (18) and capacity to volunteer.
2. Understand their rights as a research subject and are willing and able to sign a Statement of Informed Consent.
3. Willing and able to follow the protocol.
4. Agree not to participate in other clinical research for the duration of this study.
5. Current soft contact lens wearers, i.e. they have worn soft contact lenses within the past six months.
6. Can be satisfactorily fitted with the study lens types.
7. Willing to comply with the wear schedule (at least six days per week and for at least eight hours per day).
8. Understand the use of the care solutions and willing to comply with the instruction given in this study.
9. Own a wearable pair of spectacles which, in the opinion of the investigator, provide adequate vision in each eye.

Participant type(s)
Healthy volunteer

Age group
Adult

Lower age limit
18 Years

Sex

Both

Target number of participants
15

Total final enrolment
20

Key exclusion criteria
1. Ocular disorder which would normally contra-indicate contact lens wear or the care solutions used in the study.
2. Systemic disorder which would normally contra-indicate contact lens wear or the care solutions used in the study.
3. Topical medication such as eye drops or ointment.
4. Cataract surgery.
5. Corneal refractive surgery.
6. Corneal distortion or have keratoconus.
7. Pregnant or lactating.
8. Currently on immunosuppressive medication.
9. Ocular abnormality which would, in the opinion of the investigator, normally contraindicate contact lens wear.
10. Infectious disease which would, in the opinion of the investigator, contraindicate contact lens wear or pose a risk to study personnel; or they have any immunosuppressive disease (e.g. HIV), or a history of anaphylaxis or severe allergic reaction.
11. Taken part in any other contact lens or care solution clinical trial or research within two weeks prior to starting this study.

Date of first enrolment
13/11/2017

Date of final enrolment
29/12/2017

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Eurolens Research, The University of Manchester
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Sponsor type
University/education

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ROR
https://ror.org/027m9bs27

Funder(s)

Funder type
Government

Funder Name
The Government of Malaysia

Results and Publications

Publication and dissemination plan
We plan to publish this study at the Cornea journal

Intention to publish date
21/04/2019

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are not expected to be made available due to all the relevant summary data will be made available in the publication.

IPD sharing plan summary

Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		01/02/2020	21/05/2021	Yes	No