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An investigation of the inflammatory response in soft contact lens wear

Submission date
20/03/2019

Recruitment status
No longer recruiting

Registration date
21/03/2019

Overall study status
Completed

Last Edited
29/03/2021

Condition category
Eye Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

Plain English summary of protocol

Background and study aims
The literature currently indicates that contact lens wear may stimulate the inflammatory response of the ocular surface. Those publications have reported that soft contact lens wear triggers more of an inflammatory response than rigid lens wear. The inflammatory response has been speculated to be a main contributing factor to contact lens discomfort.

This work aims to investigate if a low-grade inflammatory response of the ocular surface takes place during normal contact lens wear. This will be investigated in three different types of soft contact lens. These contact lenses 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 results from this work may help us to understand more fully the effect of a contact lens on-eye and aid in the future development of contact lenses.

Who can participate?
We require 20 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, the Optometrist investigator will examine your eyes and a low powered lens will be fitted to one eye. You will be required to wear your own spectacles over the lens. Over the six week study period, you will wear the lens on alternate weeks i.e. for three weeks in total. For the three one week interim periods between the lens-wearing weeks, you will be asked to wear your own spectacles i.e. not to wear any contact lenses at all. Three examinations to assess the ocular surface will also be carried out: tear fluid collection, 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?
March 2017 to June 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

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
ER16-606

Study information

Scientific Title
Investigation of eye response to different contact lens materials and modality

Study objectives
To investigate the inflammatory response of the ocular surface in different types/modalities of soft contact lens wear, and its association with comfort.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 06/03/2017, University Research Ethics Committee (2) (The University of Manchester, Oxford Rd, Manchester, M13 9PL; 0161 275 2167; clinicaltrials@manchester.ac.uk), 2017-0621-2045.

Study design
Randomised subject-masked crossover single-centre trial

Primary study design
Interventional

Study type(s)
Other

Health condition(s) or problem(s) studied
Subclinical inflammation of the ocular surface

Interventions
Twenty soft contact lens wearers were recruited and instructed to wear three different types of soft contact lens (for one week each) in random sequence, with a one week washout period in between each lens type. All lenses (very low power) worn in one eye only on a daily wear basis and the other eye acted as a control (no lens wear). Subjects were then required to wear their own spectacles on top of the study lens as well as during the washout periods.

The study lenses were:
1) Acuvue 2 (reusable modality)
2) Acuvue Oasys with Hydraclear Plus (reusable modality)
3) Acuvue Oasys with Hydraclear Plus (daily disposable modality)

Subjects were required to attend six visits – a dispensing visit followed by a one-week follow-up visit, and this cycle was repeated three times for the three lens types.

During the dispensing visits, preliminary eye examinations including visual acuity, refraction, ocular dominance test and slit lamp biomicroscopy were carried out, followed by two main investigative examinations, in vivo confocal microscopy (under topical anaesthesia,

Oxybuprocaine hydrochloride 0.4%) and tear film collection. Subjects were then fitted with one of the study lenses and comfort score was measured using visual analogue scale (0-100). 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 afterwards. The lenses were then removed and discarded. Similar examinations as in dispensing visits were carried out with an additional investigative examination conjunctival impression cytology (under topical anaesthesia, Oxybuprocaine hydrochloride 0.4%). A complete slit lamp biomicroscopy and visual acuity examinations were then carried out. Once completed, subjects were discharged and asked to return after one week. Subjects were asked not to wear any contact lenses in order to provide a washout period before the second dispensing visit.

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.

Intervention Type
Other

Primary outcome(s)
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) Tear film: Each tear sample was analysed for 13 different types of inflammatory cytokines (Human Inflammation Panel 13-plex, BioLegend®, UK) using a cytometric bead array technique.
3) Impression cytology: Each impression sample were stained with CD45 marker (leukocyte common antigen) (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.

Key secondary outcome(s))
Association between the subclinical inflammation parameters with ocular comfort all visits (dispensing and follow-up) was statistically analysed.

Completion date
30/06/2017

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. Own a wearable pair of spectacles which, in the opinion of the investigator, provide adequate vision in each eye over the study contact lens.

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Total final enrolment
20

Key exclusion criteria
1. Ocular disorder which would normally contra-indicate contact lens wear.
2. Systemic disorder which would normally contra-indicate contact lens wear.
3. Topical medication such as eye drops or ointment.
4. Had cataract surgery.
5. Had corneal refractive surgery.
6. Any corneal distortion or have keratoconus.
7. Pregnant or lactating.
8. Currently on immunosuppressive medication
9. Any ocular abnormality which would, in the opinion of the investigator, normally contraindicate contact lens wear.
10. Any 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
20/03/2017

Date of final enrolment
15/06/2017

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Eurolens Research, The University of Manchester
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Sponsor information

Organisation
The University of Manchester

ROR
https://ror.org/027m9bs27

Funder(s)

Funder type
Government

Funder Name
The Goverment of Malaysia

Results and Publications

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	29/03/2021	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes