ISRCTN28339062 https://doi.org/10.1186/ISRCTN28339062

Evaluating the comfort, vision and fit of soft, spherical contact lenses in nearsighted and farsighted individuals.

Submission date 14/12/2018	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 18/12/2018	**Overall study status** Completed	
Last Edited 12/07/2019	**Condition category** Eye Diseases	

Plain English summary of protocol

Background and study aims

There are different kinds of vision problems that are difficult to correct by wearing glasses or contact lenses. Hyperopia, or farsightedness, is a common vision problem affecting about a quarter of the population. People who are farsighted can see far away objects well but have difficulty focusing on objects up close. This can cause headaches or eyestrain. Near sightedness, or myopia, is the most common condition of the eye. Near sighted people have difficulty reading road signs and seeing far away objects clearly, but are able to see well for close up tasks such as reading and computer use. This can cause squinting, eyestrain and headaches and fatigue while driving or playing sports. The Ocutec family of contact lenses are designed to fix both near and far sightedness. Ocutec's new contact lens, the Ocutec PEG lens, is based on a new material that is made to improve the quality of the contact lens wearing experience, provide a healthier lens and improve eyesight. The aim of this study is to compare Ocutec's lens with an established brand, assessing the comfort, vision and fit of the lenses.

Who can participate?

Adults contact lens wearers who require visual correction in both eyes

What does the study involve?

Participants are given two different types of contact lenses to wear in their eyes for 8 hours, either Ocutec's PEG or an existing contact lens (Alcon Dailies® Total 1 ®). Participants are randomly allocated to see which of their eyes wear each type of contact lens. Participants are assessed twice during the study duration. The first follow-up visit measures how well the contact lenses are working, feeling and fitting after 30 minutes and the second follow-up visit measures how well the contact lenses are working, feeling and fitting after 8 hours of wear. Participants receive standard contact lens care before they put the contact lens in and during their follow-up assessments.

What are the possible benefits and risks of participating?
There are no direct benefits to participants. There are general risks of wearing daily contact lenses however as they are worn for a short amount of time in this study the risks are not significant.

Where is the study run from?
Visioncare Research Clinic (UK)

When is the study starting and how long is it expected to run for?
January 2019 to August 2019 (updated 04/06/2019, previously: March 2019)

Who is funding the study?
Ocutec Ltd (UK)

Who is the main contact?
Ms Michelle Kerr
michelle.kerr@ocutec.com
(updated 09/07/2019, previously: Mr Graeme Beaton
graeme.beaton@ocutec.com)

Contact information

Type(s)
Public

Contact name
Ms Michelle Kerr

Contact details
3 Clark Way
Bellshill
United Kingdom
ML4 3NX
+44 (0)1698 849876
michelle.kerr@ocutec.com

Additional identifiers

Protocol serial number
PEGA-2805

Study information

Scientific Title
Assessment of the clinical performance of Ocutec PEGLens spherical soft lenses in borate buffered saline in comparison with a control soft contact lens, Alcon Dailies® Total 1®.

Study objectives
The aim of this study is to assess the clinical performance of PEG spherical soft lenses in comparison with a control soft contact lens.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 20/03/2019, London - South East Research Ethics Committee (Barlow House, 3rd Floor, 4 Minshull Street, Manchester, M1 3DZ, UK, Tel: +44 (0)207 104 8002; Email: NRESCommittee.London-SouthEast@nhs.net), REC ref: 19/LO/0187

Primary study design
Interventional

Study design
One-day randomised double-masked contralateral study

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Nearsightedness and farsightedness.

Interventions
Participants are given contact lenses to wear contralaterally for 8 hours. Participants are instructed to wear either a Ocutec PEG spherical soft lenses in one eye and a control soft contact lens Acuvue OASYS® in the other eye. The eye to which each lens is worn is assigned randomly. A random number generator (Microsoft Excel) determines the randomisation of lenses to subjects, which is then incorporated into the Randomisation Log. ID numbers (a six-digit code, made up of the study identifier (PG), the two-digit subject enrolment number and the initial letters of their first and last names) is assigned consecutively to maintain randomisation.

Visit 1: Participants are assessed at baseline and receive standard contact lens care (eye examination and measurements). Participants are then given the contact lens to wear and they insert them in their eyes. Lenses are allowed to settle for a minimum of 10 minutes prior for initial assessment of fit, comfort and for vision. Participants have two follow up visits during the study. After the lens fit the subjects remain in the clinic until the 30 minutes post insertion for their first follow up. After 30 minutes of wear, participants are assessed for comfort, lens preference, vision, lens surface and lens fit. Participants must show acceptable lens fit with both lenses and must be corrected to 0.20 logMAR (6/9) or better for binocular distance VA (over-spectacle correction may be used if required). If the lenses do not display suitable fitting, or the subject is unable to achieve 0.20 logMAR or better distance VA then they are discontinued from the study and an Exit form is completed. The Participant Instruction Guide is provided to all subjects which contains instructions regarding lens wear. The Investigator or a clinical assistant reviews instructions and warnings for lens wear and other important issues with the participant. Participants who appear unable or unwilling to follow instructions to a degree that, in the Investigator’s opinion, jeopardises the participant’s wellbeing or the validity of the study, are discontinued.

Visit 2: The 8-hour follow-up visit is scheduled 8 hours (±60 minutes) from the initial lens insertion time. The participants attend this visit having worn the study lenses continuously since Visit 1. If the participant has removed the lenses for any reason then the participant is exited from the study and the reason(s) are documented on the Exit Visit CRF. Participants are assessed

for comfort, lens preference, vision, lens surface and lens fit as well as handle-ability upon removal of the lenses. Following this assessment, worn lenses are discarded on-site.

Participants are given a study exit form for when the study has finished. This includes the patients permanent record and the details of the study. Post-study follow-up visits are scheduled if the investigator judges they are necessary and therefore the exit forms are not given to those participants until after their extra follow up visits.

Intervention Type
Device

Primary outcome(s)
1. Comfort is assessed by the subject is assessed by the subject at 30 minutes and 8 hours
2. High contrast VA is measured using computer-generated logMAR charts at 30 minutes and 8 hours
3. Non-invasive break-up time is measured using the Keeler Tearscope® and grid at 30 minutes and 8 hours
4. Pre-lens tear film quality is measured by slit lamp examination at 30 minutes and 8 hours
5. Overall lens fit is measured by slit lamp examination after at 30 minutes and 8 hours

Key secondary outcome(s)
1. Bulbar hyperaemia (0-4) is measured by Slit Lamp examination at 30 minutes and 8 hours or at another time if the subject is discontinued from the study early
2. Corneal staining (0-4) is measured by Slit Lamp examination at 8 hours or at another time if the subject is discontinued from the study early

Completion date
31/08/2019

Eligibility

Key inclusion criteria
1. ≥18 years old
2. Willing to wear supplied over-spectacle correction if required
3. Existing soft contact lens wearers (at least 4 weeks daily wear prior to study).
4. Require a visual correction in both eyes (monovision allowed but no monofit).
5. Have a spherical contact lens requirement in the range of -1.00D to -4.00D.
6. Have no greater than 1.00D difference in contact lens spherical requirement between eyes.
7. Have astigmatism <1.25D in both eyes.
8. Monocular distance visual acuity correctable to 6/9 (20/30) or better in each eye with sphero-cylindrical refraction.
9. Have normal eyes with no evidence of any ocular abnormality or disease. For the purposes of this study a normal eye is defined as one having:
9.1. Clear central corneas
9.2. No anterior segment disorder
9.3. No clinically significant slit lamp findings (i.e. corneal oedema, staining, central scarring, infiltrates, active neovascularisation)
9.4. No other active ocular disease or recent surgery

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

Key exclusion criteria
1. Any systemic disease affecting ocular health
2. Any systemic or topical medications that will in the investigator’s opinion affect ocular physiology or contact lens performance
3. Severe insufficiency of lacrimal secretion (moderate to severe dry eyes) that would affect the wearing of contact lenses
4. Persistent, clinically significant corneal or conjunctival staining using fluorescein dye (≥ Grade 3)
5. Aphakic
6. Undergone corneal refractive surgery
7. Participating in any other type of eye related clinical or research study
8. Pregnancy, lactating or planning a pregnancy at the time of enrollment
9. Participation in any trial within the last 14 days

Date of first enrolment
01/01/2019

Date of final enrolment
31/07/2019

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Visioncare Research Clinic
Craven House
West Street
Farnham
United Kingdom
GU9 7EN

Sponsor information

Organisation
Ocutec Ltd

ROR
https://ror.org/00wsb3r63

Funder(s)

Funder type
Industry

Funder Name
Ocutec Ltd

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from VisionCare Research Limited (g.woodward@visioncare.co.uk).

IPD sharing plan summary
Available on request

Study outputs

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