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Ocutec daily disposable contact lens comfort evaluation

Submission date	Recruitment status	[X] Prospectively registered
07/10/2015	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
04/11/2015	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
01/06/2018	Eye Diseases	[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
The Ocutec family of contact lenses are designed for the correction of near and far sightedness. Hyperopia, or farsightedness, is a common vision problem, affecting about a quarter of the population. People with hyperopia can see distant objects very well, but have difficulty focusing on objects that are up close. Farsighted people sometimes have headaches or eyestrain and may squint or feel fatigued when performing work at close range. Near sightedness, or myopia, is the most common condition of the eye, and it has become more common in recent years. If you are near sighted, you typically will have difficulty reading road signs and seeing distant objects clearly, but will be able to see well for close-up tasks such as reading and computer use. Other signs and symptoms of myopia include squinting, eyestrain and headaches. Feeling fatigued when driving or playing sports also can be a symptom of uncorrected near sightedness. Ocutec's lens is based on a new material that is designed to improve the quality of the contact lens wearing experience and provide a healthier lens. The aim of this study is to compare Ocutec's lens with an established brand, assessing the comfort and fit of the lenses.

Who can participate?
Volunteers aged 18 or over who wear glasses or contact lenses.

What does the study involve?
Each participant wears an Ocutec lens in one eye and an established brand of lens in the other eye for a period of 8 hours and is assessed at three different times throughout the day: on inserting the lens, after 30 minutes wear and then again after 8 hours wear. All volunteers undergo the same assessments, testing the ease of handling of the lens, comfort, vision and the fit of the lens.

What are the possible benefits and risks of participating?
There may not be any direct benefits to the volunteers in this study, but the study may contribute to scientific research that could be used to develop new products. This is low risk study, based on international standards. The risk to volunteers is further reduced as the lenses are only on the eye for 8 hours and will be monitored closely by the investigator. Complications

that may occur during the wear of the lens include discomfort, dryness, aching or itchy eyes, and blurred vision. There is also a small risk of infection, although contact lens related infections are very rare the possibility does still exist.

Where is the study run from?
Visioncare Research, Craven House, Surrey, UK.

When is the study starting and how long is it expected to run for?
November 2015

Who is funding the study?
Ocutec Ltd (UK)

Who is the main contact?
Dr Graeme Young
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Contact information

Type(s)
Public

Contact name
Ms Tamera Smith

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Ocutec Ltd
3 Clark Way
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Type(s)
Scientific

Contact name
Dr Roderick Bowers

Contact details
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
2802-2803

Study information

Scientific Title
Ocutec daily disposable contact lens comfort evaluation: a randomised double-masked contralateral study

Study objectives
To assess the clinical performance of PEG and PEG silicone spherical soft lenses in comparison with a control soft contact lens.

Ethics approval required
Old ethics approval format

Ethics approval(s)
West of Scotland Research Ethics Service, 18/12/2015, ref: 15/WS/0244

Study design
One-day randomised double-masked contralateral study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Treatment

Participant information sheet
Please see additional files

Health condition(s) or problem(s) studied
Myopia and hyperopia

Interventions
Each subject will wear a test lens in one eye and a control lens in the other for a period of 8 hours and will be assessed at three different time-points throughout the day: on insertion, after 30 minutes wear and then again at exit after 8 hours wear.

Subjective assessments: ease of handle-ability on insertion, monocular comfort on insertion. Lens fit assessment: centration, corneal coverage, post blink movement, version lag, edge tightness, tightness on push up, diameter acceptance, overall fit acceptance, overall fit

preference.
Lens surface assessment: wettability, non-invasive break-up time, pre-lens tear film quality, front surface deposits, surface preference.
Slit lamp assessment: bulbar conjunctival hyperaemia, limbal hyperaemia, tarsal hyperaemia.
Vision: monocular high and low contrast-distance visual acuity, spherical over-refraction, monocular high and low contrast VAs with over-refraction

Intervention Type
Device

Primary outcome measure
1. Overall comfort at the 8 hour visit
2. High contrast visual acuity with over-refraction at the 8 hour visit
3. Non-invasive break up time at the 8 hour visit
4. Lens wettability at the 8 hour visit
5. Overall fit acceptance at the 8 hour visit

All the outcome measure will be assesses using standard optometry equipment and metrology and patient interviews and observation.

Secondary outcome measures
1. Bulbar hyperaemia at the 8 hour visit
2. Corneal staining at the 8 hour visit

All the outcome measure will be assesses using standard optometry equipment and metrology and patient interviews and observation.

Overall study start date
01/12/2015

Completion date
07/01/2016

Eligibility

Key inclusion criteria
1. Be at least 18 years old and full legal capacity to volunteer
2. Read, understand and sign written statement of informed consent
3. Appears able and willing to follow instructions and maintain the appointment schedule
4. Existing soft contact lens wearer (at least 4 weeks daily wear prior to study)
5. Require a visual correction in both eyes (monovision allowed but no monofit)
6. Have a spherical contact lens requirement in the range of -1.00 to -4.00 DS
7. Have no greater than 1.00 DS difference in contact lens spherical requirements between eyes
8. Have astigmatism <1.25DC in both eyes
9. Monocular distance visual acuity correctable to 6/9 (20/40) or better in each eye best sphero-cylindrical refraction
10. Have normal eyes with no evidence of any ocular abnormality or disease. For the purpose of the study a normal eye is defined as having one of these:
10.1. Clear central cornea
10.2. No anterior segment disorder
10.3. No clinically significant slit lamp findings (corneal oedema, staining, central scarring,

infiltrates, active neovascularisation)
10.4. No other active ocular disease or recent surgery

Participant type(s)
Healthy volunteer

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
20-25

Key exclusion criteria
1. Any systematic disease affecting ocular health
2. Any systemic or topical medications that will in the investigators opinion affect ocular physiology or contact lens performance
3. Have severe insufficiency of lacrimal secretion (moderate to severe dry eyes) that would affect the wearing of the contact lenses
4. Has persistent, clinically significant corneal or conjuctival staining using fluorescein dye (> Grade 3)
5. Is aphakic
6. Has undergone corneal refractive surgery
7. Is participating in any other type of eye-related clinical or research study
8. Pregnancy, lactating or planning a pregnancy at the time of enrolment

Date of first enrolment
01/12/2015

Date of final enrolment
07/01/2016

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Visioncare Research
Craven House
West Street
Farnham

United Kingdom
GU9 7EN

Sponsor information

Organisation
Ocutec Ltd (UK)

Sponsor details
3 Clark Way
Bellshill
United Kingdom
ML4 3NX

Sponsor type
Research organisation

Website
www.ocutec.com

ROR
https://ror.org/00wsb3r63

Funder(s)

Funder type
Industry

Funder Name
Ocutec Ltd (UK)

Results and Publications

Publication and dissemination plan
No publications expected

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet			13/04/2016	No	Yes
HRA research summary			28/06/2023	No	No