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Comparison of contact lenses for correction of presbyopia

Submission date 04/04/2023	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 04/04/2023	**Overall study status** Completed	
Last Edited 04/04/2023	**Condition category** Eye Diseases	

Plain English summary of protocol

Background and study aims
As adults get older, they develop a need for an additional prescription for their reading vision. This can be provided by soft contact lenses, called multifocal contact lenses which offer a prescription for their distance vision and their near vision. There are a number of different designs available on the market. This study aims to compare a marketed multifocal contact lens with a contact lens design not available on the market.

Who can participate ?
Adults who are current multifocal soft contact lens wearers

What does the study involve ?
The participants will attend a total of three visits as described below.
Participants will attend the clinic on three separate occasions approximately one week apart. Two different contact lenses will be dispensed at the first two visits and to be worn for approximately a week. At visits 2 and 3 the acceptance will be assessed by the investigators.

What are the possible benefits and risks of participating ?
Participants have the opportunity to try contact lenses to correct their presbyopia. Any contact lens wear comes at the risk of corneal infection, but the incidence rate is very low.

Where is the study run from?
Ocular Technology Group - International (OTG-i) (UK)

When is the study starting and how long is it expected to run for?
January 2022 to June 2024

Who is funding the study?
Brien Holden Vision Institute (BHVI) (Australia)

Who is the main contact?
Deborah Moore, DMoore@otg.co.uk (UK)

Contact information

Type(s)
Public

Contact name
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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
322080

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
CRTC2022-01 ID22-37, IRAS 322080

Study information

Scientific Title
CREST EDOF Contact Lenses vs MyDay contact lenses

Acronym
CRIMSON

Study objectives
The hypothesis to be tested will be that the visual acceptance, reported in terms of overall binocular vision satisfaction, of test contact lenses for presbyopia is non-inferior to that of control contact lenses.

Ethics approval required
Old ethics approval format

Ethics approval(s)

Approved 22/02/2023, North of Scotland Research Ethics Committee 2 (2nd Floor, Waverley Gate, 2-4 Waterloo Place, Edinburgh, EH1 3EG, UK; +44 (0)1315369000; ruth.fraser4@nhslothian.scot.nhs.uk), ref: 23/SS/0009

Study design
Two-arm prospective double-masked randomized crossover trial

Primary study design
Interventional

Secondary study design
Randomised cross over trial

Study setting(s)
Other

Study type(s)
Treatment

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
Presbyopia

Interventions
Randomisation is carried out by a standard computer randomisation generator software. Two types of contact lenses will be worn by each participant in a random order in turn for approximately one week on a daily disposable basis. Each participant attends the clinic on three occasions: the first visit for enrolment, screening and contact lens order 1 dispense, visit 2 for contact lens order 1 follow-up and contact lens order 2 dispense, and visit 3 for contact lens order 2 follow-up and discharge.

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
CREST EDOF, MyDay Multifocal

Primary outcome measure
Overall binocular vision satisfaction measured using a 0-100point Visual Analogue Scale (VAS) with anchor descriptors of 0 = Extremely Unsatisfied and 100 = Extremely satisfied, after 1 week of contact lens wear

Secondary outcome measures

Mean binocular visual acuity, measured as the mean visual acuity of overall distance and overall near visual acuities, after 1 week of contact lens wear

Overall study start date
21/01/2022

Completion date
01/06/2024

Eligibility

Key inclusion criteria
1. 40 or more years of age
2. Current multifocal contact lens wearer
3. Spectacle refraction:
3.1. Distance: Sphere: -5.00D to + 3.00D
3.2. Astigmatism: 0.00 to -0.75D
3.3. Near Spectacle Addition at 40cm
3.4. Medium add presbyopes: +1.50D and +1.75D
3.5. High add presbyopes: +2.00D to +2.50D
4. Best corrected visual acuity of at least 20/25 in each eye
5. Participant has read and understood the Participant Information Sheet
6. Participant has read, signed and dated the Informed Consent
7. Participant willing and able to adhere to the instructions set in the clinical protocol and maintain the appointment schedule

Participant type(s)
Patient

Age group
Adult

Lower age limit
40 Years

Sex
Both

Target number of participants
45

Total final enrolment
35

Key exclusion criteria
1. Acute and subacute inflammation or infection of the anterior chamber of the eye
2. Any eye disease, injury or abnormality that affects the cornea, conjunctiva or eyelids that would contraindicate contact lens wear
3. Corneal hypoesthesia (reduced corneal sensitivity), if not aphakic

4. Severe insufficiency of lacrimal secretion (dry eyes)
5. Any systemic disease that may affect the eye or may be exaggerated by wearing contact lenses (e.g. acne and eczema)
6. Allergic reactions of ocular surfaces or adnexa that may be induced or exaggerated by wearing contact lenses or use of contact lens solutions
7. Any active corneal infection (bacterial, fungal, protozoal or viral)
8. Newly prescribed (within the past 30 days) use of some systemic medications (such as antihistamines, decongestants, diuretics, muscle relaxants, tranquilizers, stimulants, anti-depressants, anti-psychotics, oral contraceptives) or new prescription eyedrops which is not rewetting/lubricating eyedrops for which contact lens wear could be contraindicated as determined by the investigator
9. Monocular participants (only one eye with functional vision) or participants fit with only one lens
10. Subjects with slit lamp findings greater than grade 1 (e.g. edema, infiltrates, corneal neovascularization, corneal staining, tarsal abnormalities, conjunctival, anterior segment inflammation) as per ISO 11980, any previous history or signs of a contact lens related corneal inflammatory event (past corneal ulcers), or any other ocular abnormality that may contraindicate contact lens wear at the enrolment visit
11. History of corneal refractive surgery
12. Enrolment of the family members of the investigator, family members of the investigator's staff, or individuals living in the households of these individuals
13. Current wearer of the control contact lenses, MyDay® Multifocal

Date of first enrolment
07/04/2023

Date of final enrolment
01/12/2023

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Ocular Technology Group – International
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Sponsor information

Organisation

Brien Holden Vision Institute

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Sponsor type
Research organisation

Website
http://www.brienholdenvision.org/

ROR
https://ror.org/00g1p6865

Funder(s)

Funder type
Research organisation

Funder Name
Brien Holden Vision Institute

Alternative Name(s)

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
Australia

Results and Publications

Publication and dissemination plan
There are no plans at this stage for publication or dissemination

Intention to publish date
01/01/2025

Individual participant data (IPD) sharing plan
The data sharing plans for this study are unknown at this stage and will be made available at a later date.

IPD sharing plan summary
Data sharing statement to be made available at a later date