

# Comparison of contact lenses for correction of presbyopia

<b>Submission date</b> 04/04/2023	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 04/04/2023	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 04/04/2023	<b>Condition category</b> Eye Diseases	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

## 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**

66 Buckingham Gate

London

United Kingdom

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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