

# Comparison of soft contact lenses for myopia control

<b>Submission date</b> 13/02/2023	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 13/02/2023	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 25/02/2026	<b>Condition category</b> Eye Diseases	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

### Background and study aims

The number of adolescents with myopia (short-sightedness) has been increasing very rapidly over the last 10 - 20 years. The concern is that short-sighted eyes are more likely to develop ocular pathology (eye disease) than normal eyes from the age of 60+ years. Therefore various methods are being developed to minimise short-sightedness and prevent potential problems later in life. The aim of this study is to compare the acceptance of a new design of contact lens with a currently marketed option.

### Who can participate?

Children aged 12 to 18 years who are current 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 about 1 week apart. Two different contact lenses will be dispensed at the first two visits and to be worn for about a week. At visits 2 and 3 the participants' acceptance of the contact lenses will be assessed by the investigators.

### What are the possible benefits and risks of participating?

Participants have the opportunity to try contact lenses to help their vision and control the progression of their myopia. 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)

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

January 2022 to April 2024

### Who is funding the study?

Brien Holden Vision Institute (BHVI) (Australia)

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

## Contact information

### Type(s)

Public

### Contact name

Miss Deborah Moore

### Contact details

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## Additional identifiers

### Clinical Trials Information System (CTIS)

Nil known

### Integrated Research Application System (IRAS)

320023

### ClinicalTrials.gov (NCT)

Nil known

### Protocol serial number

ID22-32 CRT2022-02

## Study information

### Scientific Title

CREST EDOF Contact Lenses vs MiSight 1day contact lenses

### Acronym

Blond

### Study objectives

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

### Ethics approval required

Old ethics approval format

## **Ethics approval(s)**

Approved 10/11/2022, North of Scotland Research Ethics Committee (1) (Summerfield House, 2 Eday Road, Aberdeen, AB15 6RE, UK; +44 (0)1224 558458; gram.nosres@nhs.scot), ref: 22/NS/0134

## **Study design**

Two-arm prospective double-masked randomized crossover trial

## **Primary study design**

Interventional

## **Study type(s)**

Treatment

## **Health condition(s) or problem(s) studied**

Myopia

## **Interventions**

Randomization is carried out by a standard computer randomization generator software. Two soft contact lenses (CREST EDOF, MiSight) will be worn by each participant in a random order in turn for approximately 1 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, MiSight

## **Primary outcome(s)**

Overall binocular vision satisfaction measured using a 0-100-point Visual Analogue Scale (VAS) with anchor descriptors of 0 = Not Happy and 100 = Very Happy, measured after 1 week of contact lens wear.

## **Key secondary outcome(s)**

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

## **Completion date**

15/04/2024

## **Eligibility**

### **Key inclusion criteria**

1. Age 12 to 18 years
2. Current soft contact lens wearers
3. Parent/guardian and participant have read and understood the Participant Information Sheet
4. Parent/guardian and participant have read, signed and dated the Informed Consent and Assent (when applicable)
5. Best corrected visual acuity of at least 20/25 in each eye
6. Have normal eyes with the exception of the need for visual correction
7. Spectacle refraction: Sphere -5.00D to -1.00D, Cylinder 0.00 to -0.75D
8. Be willing and able to adhere to the instructions set in the clinical protocol and maintain the appointment schedule

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Mixed

**Lower age limit**

12 years

**Upper age limit**

18 years

**Sex**

All

**Total final enrolment**

28

**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. eczema and acne)
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

**Date of first enrolment**

20/02/2023

**Date of final enrolment**

31/12/2023

## **Locations**

**Countries of recruitment**

United Kingdom

England

**Study participating centre**

**Ocular Technology Group - International**

66 Buckingham Gate

London

England

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## **Sponsor information**

**Organisation**

Brien Holden Vision Institute

**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

**Individual participant data (IPD) sharing plan****IPD sharing plan summary**

Data sharing statement to be made available at a later date

**Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Basic results</a>	version 1.0	18/02/2026	25/02/2026	No	No
<a href="#">HRA research summary</a>			28/06/2023	No	No