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Comparison of soft contact lenses for myopia control

Submission date 13/02/2023	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 13/02/2023	**Overall study status** Completed	
Last Edited 13/02/2023	**Condition category** Eye Diseases	

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
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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
320023

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
ID22-32 CRT2022-02, IRAS 320023

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

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
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 measure
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.

Secondary outcome measures

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

Overall study start date
20/01/2022

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

Age group
Child

Lower age limit
12 Years

Sex
Both

Target number of participants
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. 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
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

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

Study outputs

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