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Evaluation of the clinical acceptance of soft contact lenses for shortsightedness in adolescents

Submission date	Recruitment status	[_] Prospectively registered
10/12/2020	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
28/01/2021	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
21/07/2021	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+. Therefore various methods are being developed to minimise short sightedness and prevent the potential problems later in life.
Studies to control the progression of myopia (increase in short-sightedness) are long-term studies lasting 3-5 years. The effectiveness of the contact lens in controlling myopia depends on the adolescent wearing the contact lens as long as possible everyday. The aim of this study is to test the visual acceptance of the prototype contact lens in the short term as a screening to their possibility of being used in a long-term study.

Who can participate?
Adolescents between the ages of 10 and 16 who require contact lenses

What does the study involve?
Three soft contact lenses will be worn in turn for 1 week by each participant in a random order. Each participant attends the clinic on five occasions: the first visit for enrolment, screening and fitting and the other four visits for contact lens dispensing and follow up measurements.

What are the possible benefits and risks of participating?
The participant can try using contact lenses to control their myopia.

Where is the study run from?
Ocular Technology Group - International Research Clinic (UK)

When is the study starting from and how long is it expected to run for?
March 2019 to September 2020

Who is funding the study?
CooperVision Inc (USA)

Who is the main contact?
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Contact information

Type(s)
Public

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
266562

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
CV19-40 ID19-21, IRAS 266562

Study information

Scientific Title
Evaluation of the clinical acceptance of soft contact lenses for myopia control

Study objectives
Visual satisfaction with a test contact lens is not inferior to the control contact lens.

Ethics approval required
Old ethics approval format

Ethics approval(s)

Approved 10/07/2019, West of Scotland REC 4 (Ward 11 Dykebar Hospital, Grahamston Road, Paisley, PA2 7DE, Scotland, UK; +44 (0)141 314 0214; WoSREC4@ggc.scot.nhs.uk), REC ref: 19/WS/0099

Study design
Prospective double-masked single-group randomized cross over study

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 the contact details to request a participant information sheet

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

Interventions
Randomisation is carried out by a standard computer randomisation generator software. Three soft contact lenses (Eni Eye Q Multifocal Contact Lenses for Daily Wear XT1, XT2 and XTC) will be worn in turn for 1 week by each participant in a random order. Each participant attends the clinic on five occasions: the first visit for enrolment, screening and fitting and the other four visits for contact lens dispensing and follow up measurements.

Intervention Type
Device

Phase
Not Applicable

Primary outcome measure
Visual satisfaction measured using the mean of three questions each recorded on a 0 -100 visual analogue scale at each visit (baseline, V1 dispense, V2 10 +/- 3 days later, V3 10 +/- 3 days later, V4 10 +/- 3 days later)

Secondary outcome measures
Visual acuity measured using high and low LogMar visual acuity charts at a distance of 4 metres during each visit (baseline, V1 dispense, V2 10 +/- 3 days later, V3 10 +/- 3 days later, V4 10 +/- 3 days later)

Overall study start date
01/03/2019

Completion date
30/09/2020

Eligibility

Key inclusion criteria
1. Age 10 to 16 years
2. Spectacle refraction: -0.75 to -6.00D spherical equivalent, maximum anisometropia 1.25D, cylinder up to -1.00DC
3. Best corrected visual acuity of at least 20/25 in each eye
4. Parents/guardians and participant have read and understood the Participant Information Sheet
5. Parents/guardians and participant have read, signed and dated the Informed Consent
6. Have normal eyes with the exception of the need for visual correction
7. 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
10 Years

Upper age limit
16 Years

Sex
Both

Target number of participants
30

Total final enrolment
20

Key exclusion criteria
1. Ocular anterior segment infection, inflammation, abnormality, or active disease that would contraindicate contact lens wear
2. Newly prescribed use of some systemic or ocular medications for which contact lens wear could be contraindicated as determined by the investigator
3. Monocular participants (only one eye with functional vision) or participants fit with only one lens
4. 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
5. History of herpetic keratitis, ocular surgery or irregular cornea
6. Enrolment of the family members of the investigator, family members of the investigator's staff, or individuals living in the households of
these individuals

Date of first enrolment
01/11/2019

Date of final enrolment
01/12/2020

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Ocular Technology Group - International
66 Buckingham Gate
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United Kingdom
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Sponsor information

Organisation
CooperVision (United States)

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Sponsor type
Industry

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Funder(s)

Funder type
Industry

Funder Name
CooperVision Inc. (USA)

Results and Publications

Publication and dissemination plan
There are no specific plans for publication or dissemination of the study results. Additional documents are not available.

Intention to publish date

Individual participant data (IPD) sharing plan
The data-sharing plans for the current study are unknown 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?
Basic results		28/01/2021	21/07/2021	No	No
HRA research summary			28/06/2023	No	No