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Clinical acceptance and performance of Hercules soft contact lenses

Submission date 09/06/2021	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 11/06/2021	**Overall study status** Completed	
Last Edited 27/04/2022	**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+. 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 and satisfaction of the contact lenses.

Who can participate?
Adolescents between the ages of 10 and 18 that require contact lenses.

What does the study involve?
Participants will attend the clinic on three separate days approximately one week apart. Two different soft contact lenses will be dispensed at visit 1 and 2 and at visits 2 and 3, participants' vision and satisfaction will be measured 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 Research Clinic (UK)

When is the study starting and how long is it expecting to run for?
June 2021 to November 2021

Who is funding the study?
CooperVision International Limited (UK)

Who is the main contact?
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Contact information

Type(s)
Public

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Integrated Research Application System (IRAS)
296709

Protocol serial number
CV20-32 ID20-67

Study information

Scientific Title
Validation study of the clinical acceptance and performance of Hercules soft contact lenses

Study objectives
1. Overall visual acuity performance with the Test contact lens is not statistically inferior to the Control contact lens after one week of wear
2. Comfort and wearing time with the Test contact lens is not statistically inferior to the Control contact lens after one week of wear

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 17/05/2021, Yorkshire & The Humber, Leeds West Research Ethics Committee (NHSBT Newcastle Blood Donor Centre, Holland Drive, Newcastle upon Tyne, NE2 4NQ, UK; +44(0)207 972 2504; leedswest.rec@hra.nhs.uk) ref: 21/YH/0074

Primary study design
Interventional

Study design
Single-centre prospective double-masked randomized crossover trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Clinical acceptance and performance of soft contact lenses

Interventions
Randomisation is carried out by a standard computer randomisation generator software. Two soft contact lenses will be worn by each participant in a random order in turn for 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)
MiSight® 1 day daily disposable contact lenses

Primary outcome(s)
Overall binocular visual performance (logMAR chart) measured after 9 - 13 days of wear

Key secondary outcome(s)
1. Overall comfort on a 100-point visual analog scale measured after 9 - 13 days of wear
2. Daily wearing time in hours measured after 9 - 13 days of wear

Completion date
30/11/2021

Eligibility

Key inclusion criteria
1. Age 8 to 18 years;
2. Current soft contact lens wearers;
3. Spectacle refraction: -0.75 to -6.00D spherical equivalent, with cylinder ≤ -0.75 DC and maximum anisometropia of <1.00D;
4. Best corrected visual acuity of at least 20/25 in each eye;
5. Parents/guardians and participant have read and understood the Participant Information Sheet;
6. Parents/guardians and participant have read, signed and dated the Informed Consent;
7. Have normal eyes with the exception of the need for visual correction;
8. Be willing and able to adhere to the instructions set in the clinical protocol and maintain the appointment schedule.

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group
Child

Lower age limit
8 Years

Upper age limit
18 Years

Sex
All

Total final enrolment
63

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
14/06/2021

Date of final enrolment
01/10/2021

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Ocular Technology Group - International
66 Buckingham Gate
London
United Kingdom
SW1E 6AU

Sponsor information

Organisation
CooperVision International Limited

Funder(s)

Funder type
Industry

Funder Name
CooperVision International Limited

Results and Publications

Individual participant data (IPD) sharing plan
The current data sharing plans for this study are unknown and will be 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	version 1.0	27/04/2022	27/04/2022	No	No
HRA research summary			26/07/2023	No	No