

Clinical acceptance and performance of Hercules soft contact lenses

Submission date 09/06/2021	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 11/06/2021	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 27/04/2022	Condition category 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+. 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?

Deborah Moore
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Contact information

Type(s)

Public

Contact name

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Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number

296709

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

CV20-32 ID20-67, IRAS 296709

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

Study design

Single-centre 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

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 measure

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

Secondary outcome measures

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

Overall study start date

01/06/2021

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 \leq -0.75 DC and maximum anisometropia of <1.00 D;
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

Age group

Child

Lower age limit

8 Years

Upper age limit

18 Years

Sex

Both

Target number of participants

90

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

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 International Limited

Sponsor details

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Sponsor type

Industry

Website

Funder(s)

Funder type

Industry

Funder Name

CooperVision International Limited

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

31/12/2021

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