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Effect of uncorrected astigmatism on vision

Submission date	Recruitment status	[_] Prospectively registered
15/08/2022	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
31/08/2022	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
06/02/2024	Eye Diseases	

Plain English summary of protocol

Background and study aims
Astigmatism is an imperfection in the curvature of the eye's cornea or lens that causes blurry vision. The aim of this study is to find out whether the overall visual performance of the study contact lens with an astigmatic correction is better than the study contact lens without an astigmatic correction.

Who can participate?
Children and adolescents aged 8-16 years old

What does the study involve?
A single visit to the study clinic where the participants will be fitted with contact lenses and wear three different pairs of spectacles providing over-corrections (one without astigmatism and two with astigmatism) and their vision with each pair of spectacles will be assessed.

What are the possible benefits and risks of participating?
The participants will be current contact lens wearers and they will use the study contact lenses under the control and care of the investigator. The study contact lenses are currently available on the market. The risks to participants are no greater than wearing their own contact lenses. In wearing the study contact lenses, they may experience an improvement in vision or comfort in a pair of contact lenses they could eventually purchase from their own practitioner.

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

When is the study starting and how long is it expected to run for?
June 2022 to March 2023

Who is funding the study?
CooperVision (UK)

Who is the main contact?
Ms Deborah Moore
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Contact information

Type(s)
Public

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
315088

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
CV-22-05 ID22-13, IRAS 315088

Study information

Scientific Title
MiSIght effect of uncorrected astigmatism on visual acuity non-dispensing study

Study objectives
The primary hypothesis to be tested will be that the overall visual performance of the study contact lens with an astigmatic correction will be superior to the overall visual performance of the study contact lens without an astigmatic correction.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 12/07/2022, London - Bloomsbury Research Ethics Committee (HRA RES Centre Manchester, 3rd Floor Barlow House, 4 Minshull Street, Manchester, M1 3DZ, UK; +44 (0) 2071048272; bloomsbury.rec@hra.nhs.uk), ref: 22/PR/0650

Study design
Single-centre double-blinded randomized crossover trial

Primary study design
Interventional

Study type(s)
Treatment

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

Interventions
Participants will be fitted with the study contact lenses per their fitting guide. Participants will then wear three pairs of spectacles in a randomised crossover fashion. The control (plano) correction provides no astigmatic correction, and the two test corrections providing an astigmatic corrections are i. +0.25DS / -0.75DC and ii. +0.50DS / -1.25DC. Participants will be wearing the study contact lenses for approximately 5 hours and will be wearing each pair of spectacle over-corrections for approximately 1.5 hours each.

Participants will wear all of the spectacle corrections in a random order. Only the investigator will know which pair of spectacles they are wearing.

While participants are wearing the spectacles, their vision will be assessed using logMAR vision charts.

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
MiSight 1-day contact lenses

Primary outcome(s)
Overall timed logMAR visual acuity measured after 20 minutes of spectacle wear

Key secondary outcome(s))
Visual acceptance measured using 0-100 VAS questions after approximately an hour and a half of wear

Completion date
01/03/2023

Eligibility

Key inclusion criteria
1. Age 8 to 16 years
2. Current soft contact lens wearers

3. Spectacle refraction: -0.75 to -6.00 D spherical equivalent, with cylinder of -0.50 DC to -1.75 DC
4. Best corrected visual acuity of at least 20/25 in each eye
5. Have normal eyes with the exception of the need for visual correction
6. Parent/guardian and participant have read and understood the Participant Information Sheet
7. Parent/guardian and participant have read, signed and dated the Informed Consent and Assent (when applicable)

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group
Child

Lower age limit
8 years

Upper age limit
16 years

Sex
All

Key exclusion criteria
To be eligible as a participant, each candidate shall be free of any ocular or medical condition that may affect the results of this study.

The following are specific criteria that exclude a candidate from enrolment in this study:
1. Ocular anterior segment infection, inflammation, abnormality, or active disease that would contraindicate contact lens wear
2. 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
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 2 or higher (e.g. oedema, 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
15/08/2022

Date of final enrolment
01/12/2022

Locations

Countries of recruitment
United Kingdom

England

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

Organisation
CooperVision International Limited

Funder(s)

Funder type
Industry

Funder Name
CooperVision

Results and Publications

Individual participant data (IPD) sharing plan
The data-sharing plans for the current 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?
Basic results	version 1.0	11/01/2024	06/02/2024	No	No
HRA research summary			28/06/2023	No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes