

# Effect of uncorrected astigmatism on vision

<b>Submission date</b> 15/08/2022	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 31/08/2022	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 06/02/2024	<b>Condition category</b> Eye Diseases	<input type="checkbox"/> Individual participant data

## 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

## Contact name

Ms Deborah Moore

## Contact details

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# Additional identifiers

## EudraCT/CTIS number

Nil known

## IRAS number

315088

## ClinicalTrials.gov number

Nil known

## Secondary identifying numbers

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

**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**

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 measure**

Overall timed logMAR visual acuity measured after 20 minutes of spectacle wear

**Secondary outcome measures**

Visual acceptance measured using 0-100 VAS questions after approximately an hour and a half of wear

**Overall study start date**

01/06/2022

**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

**Age group**

Child

**Lower age limit**

8 Years

**Upper age limit**

16 Years

**Sex**

Both

**Target number of participants**

30

**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**

England

United Kingdom

**Study participating centre**

**Ocular Technology Group - International**

66 Buckingham Gate

London

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## **Sponsor information**

**Organisation**

CooperVision International Limited

**Sponsor details**

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**Sponsor type**

Industry

**Website**

<http://coopervision.com>

## Funder(s)

**Funder type**

Industry

**Funder Name**

CooperVision

## Results and Publications

**Publication and dissemination plan**

There are no plans for publication or dissemination of the study results.

**Intention to publish date**

01/12/2023

**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?
<a href="#">HRA research summary</a>			28/06/2023	No	No
<a href="#">Basic results</a>	version 1.0	11/01/2024	06/02/2024	No	No