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Correction of low astigmatism

Submission date 22/09/2023	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 29/09/2023	**Overall study status** Completed	
Last Edited 30/01/2024	**Condition category** Eye Diseases	

Plain English summary of protocol

Background and study aims
Astigmatism is a common eye problem that can make vision blurry or distorted. People with astigmatism can be corrected with spectacles or contact lenses. When corrected with spectacles any level of astigmatism present is always corrected. In contrast, when corrected with contact lenses low level of astigmatism is usually not corrected in routine practice. A number of studies have suggested that this approach may produce less than optimal vision in particular at night. The aim of this study is to demonstrate that low astigmatic contact lens wearers could benefit from using toric contact lenses (contact lenses that correct astigmatism) instead of standard spherical contact lenses.

Who can participate?
Adults aged 18 to 35 years who are current soft contact lens wearers and have low levels of astigmatism

What does the study involve?
Participants will attend the clinic on three separate occasions approximately one week apart. Two different contact lenses will be dispensed at the first two visits and to be worn for about a week. At visits 2 and 3 the acceptance will be assessed by the investigators.

What are the possible benefits and risks of participating?
Participants have the opportunity to try contact lenses to correct their astigmatism. 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 (OTG-i) (UK)

When is the study starting and how long is it expected to run for?
April 2023 to June 2024

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

Who is the main contact?
Deborah Moore, dmoore@otg.co.uk

Contact information

Type(s)
Public

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
331203

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
CV23-42 ID23-35, IRAS 331203

Study information

Scientific Title
Correction of low level of astigmatism with soft contact lenses

Study objectives
The primary hypothesis to be tested is that the visual acuity under mesopic light conditions with the test toric contact lens is superior to that with the control spherical contact lens.

The secondary hypotheses to be tested are that:
1. Night-time vision satisfaction with the test toric contact lens is superior to that with the control spherical contact lens
2. Visual acuity in the presence of glare with the test toric contact lens is superior to that with the control spherical contact lens

Ethics approval required
Ethics approval required

Ethics approval(s)

approved 31/08/2023, North Of Scotland Ethics Committee 02 (Summerfield House, 2 Eday Road, Aberdeen, AB15 6RE, United Kingdom; +44 (0)1224558458; gram.nosres@nhs.scot), ref: 23/NS/0081

Study design
Single-centre prospective interventional double-masked cross-over randomized trial

Primary study design
Interventional

Study type(s)
Efficacy

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

Interventions
Two types of contact lenses (MyDay Toric®, MyDay® spherical) will be worn by each participant in a random order in turn for at least 7 days (7 -0./+3 days) on a daily disposable basis. Randomisation is carried out by a standard computer randomisation generator software. Each participant attends the clinic on three occasions: the first visit for enrolment, screening and contact lens order 1 dispensing, visit 2 for contact lens order 1 follow-up and contact lens order 2 dispensing, and visit 3 for contact lens order 2 follow-up and discharge.

Intervention Type
Device

Phase
Phase IV

Drug/device/biological/vaccine name(s)
MyDay Toric®, MyDay® spherical

Primary outcome(s)
Timed monocular logMAR high contrast (>90%), mesopic (2.5 cd/m2) visual acuity measured at the follow-up visits at 7 (+3/-0), 14 (+3/-0) and 21 (+3/-0) days

Key secondary outcome(s))
1. Overall night-time vision satisfaction recorded on a 100-point VAS measured at the follow-up visits at 7 (+3/-0), 14 (+3/-0) and 21 (+3/-0) days
2. Timed monocular logMAR medium contrast, mesopic (2.5 cd/m2) visual acuity loss with the addition of a glare source measured at the follow-up visits at 7 (+3/-0), 14 (+3/-0) and 21 (+3/-0) days

Completion date
01/06/2024

Eligibility

Key inclusion criteria

In order to be enrolled, each participant shall meet the following criteria:
1. Aged 18 to 35 years
2. Current contact lens wearer
3. Spectacle refraction:
Distance: Sphere: -6.00D to + 2.00D
Astigmatism: -0.50D to -1.00D with at least -0.75D in one eye
4. Best corrected visual acuity of at least 20/25 in each eye

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Upper age limit
35 years

Sex
All

Total final enrolment
25

Key exclusion criteria
1. Acute and subacute inflammation or infection of the anterior chamber of the eye
2. Any eye disease, injury or abnormality that affects the cornea, conjunctiva or eyelids that would contraindicate contact lens wear
3. Corneal hypoesthesia (reduced corneal sensitivity), if not aphakic
4. Severe insufficiency of lacrimal secretion (dry eyes)
5. Any systemic disease that may affect the eye or may be exaggerated by wearing contact lenses (e.g. acne and eczema)
6. Allergic reactions of ocular surfaces or adnexa that may be induced or exaggerated by wearing contact lenses or use of contact lens solutions
7. Any active corneal infection (bacterial, fungal, protozoal or viral)
8. 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
9. Monocular participants (only one eye with functional vision) or participants fit with only one contact lens
10. 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
11. History of corneal refractive surgery
12. Enrolment of the family members of the investigator, family members of the investigator's staff, or individuals living in the households of these individuals
13. Current wearer of the control contact lenses MyDay® spherical or the test contact lenses MyDay Toric®

Date of first enrolment
22/09/2023

Date of final enrolment
31/12/2023

Locations

Countries of recruitment
United Kingdom

England

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

Organisation
CooperVision International Ltd

Funder(s)

Funder type
Industry

Funder Name
CooperVision International Ltd

Results and Publications

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

Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Basic results		18/01/2024	30/01/2024	No	No