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Benefits of fitting non contact lens wearers with astigmatism with MyDay® 1-day toric contact lenses

Submission date 18/03/2025	**Recruitment status** Recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [X] Record updated in last year
Registration date 26/03/2025	**Overall study status** Ongoing	
Last Edited 18/03/2025	**Condition category** Eye Diseases	

Plain English summary of protocol

Background and study aims
Some clinical evidence suggests that eye discomfort with soft toric contact lenses is different to that experienced by spherical soft contact lens wearers.
The aim of this study is to assess and compare eye comfort during contact lens wear with spherical and toric soft contact lenses in population of non contact lens wearers.

Who can participate?
Adults aged 18 to 35 years with no previous contact lens wearing experience
astigmatism (imperfection in the curvature of the eye)

What does the study involve?
The participants will attend the clinic for two study visits and will complete a series of questionnaires while wearing the study contact lenses. At the first visit the participant will be fitted with the relevant study contact lenses MyDay spherical for the control group and MyDay toric for the test group.
The study contact lenses will be worn for one month under daily disposable wearing modality. At visit 2 comfort and the vision satisfaction 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 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?
March 2025 to October 2025

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

Who is the main contact?
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Contact information

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Scientific, Principal Investigator

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Public

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
354030

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Nil known

Study information

Scientific Title
Benefits of fitting neophyte astigmat with MyDay® 1-Day toric contact lenses

Study objectives
The primary hypothesis to be tested is that ocular comfort of neophytes astigmats fitted with the MyDay® 1-Day toric contact lenses is non-inferior to ocular comfort of neophytes non-astigmats or exhibiting very low astigmatism fitted with MyDay® 1-Day Asphere contact lenses.
The secondary hypothesis to be tested is that the vision satisfaction of neophytes astigmats fitted with the MyDay® 1-Day toric contact lenses is non-inferior to vision satisfaction of neophytes non-astigmats or exhibiting very low astigmatism fitted with MyDay® 1-Day Asphere contact lenses.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 12/03/2025, North of Scotland Research Ethics Committee (Summerfield House, 2 Eday Road, Aberdeen, AB15 6RE, United Kingdom; +44 1224558458; gram.nosres@nhs.scot), ref: 25/NS/0025

Study design
Interventional open-label prospective investigator masked study following a parallel group study design

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Other

Study type(s)
Efficacy

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
Astigmatism

Interventions
The participants will attend the clinic for two study visits and will complete a series of questionnaires while wearing the study contact lenses. At the first visit the participant will be fitted with the relevant study contact lenses MyDay spherical for the control group and MyDay toric for the test group.
The study contact lenses will be worn for one month under daily disposable wearing modality. At visit 2 comfort and the vision satisfaction will be assessed by the investigators.

Intervention Type
Device

Pharmaceutical study type(s)
Not Applicable

Phase
Phase IV

Drug/device/biological/vaccine name(s)
MyDay® 1-Day Toric® & MyDay® 1-Day Asphere

Primary outcome measure
Ocular comfort on a 100-point visual analog scale during the one month study visit

Secondary outcome measures
Vision satisfaction on a 100-point visual analog scale during the one month study visit.

Overall study start date
04/01/2025

Completion date
31/10/2025

Eligibility

Key inclusion criteria
1. Age 18 to 35 years
2. No previous contact lens wearing experience
3. Spectacle refraction:
Sphere: -6.00D to + 2.00D
Astigmatism:
Control group: 0.00D to -0.50D in each eye
Test group: -0.75D to -2.00D in each eye
4. Best corrected visual acuity of at least 20/25 in each eye

Participant type(s)
Healthy volunteer

Age group
Adult

Lower age limit
18 Years

Upper age limit
35 Years

Sex
Both

Target number of participants
50

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.

Date of first enrolment
30/03/2025

Date of final enrolment
31/10/2025

Locations

Countries of recruitment
England

United Kingdom

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

Organisation
CooperVision International Limited

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Sponsor type
Industry

Website
https://coopervision.com

Funder(s)

Funder type
Industry

Funder Name
CooperVision

Alternative Name(s)
CooperVision, Inc., CooperVision Inc, CooperVision Inc., CooperVision, Inc

Funding Body Type
Government organisation

Funding Body Subtype
For-profit companies (industry)

Location
United States of America

Results and Publications

Publication and dissemination plan
There are no plans at this stage for publication or dissemination.

Intention to publish date

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
Not expected to be made available