

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

Submission date 18/03/2025	Recruitment status No longer recruiting	☒ Prospectively registered ☐ Protocol
Registration date 26/03/2025	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 12/02/2026	Condition category Eye Diseases	☐ Individual participant data

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?
Deborah Moore, dmoore@otg.co.uk

Contact information

Type(s)

Scientific, Principal investigator

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Public

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Additional identifiers

Integrated Research Application System (IRAS)
354030

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

Primary study design

Interventional

Study design

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

Study type(s)

Efficacy

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

Phase

Phase IV

Drug/device/biological/vaccine name(s)

MyDay® 1-Day Toric® & MyDay® 1-Day Asphere

Primary outcome(s)

Ocular comfort on a 100-point visual analog scale during the 1-month study visit

Key secondary outcome(s)

Vision satisfaction on a 100-point visual analog scale during the 1-month study visit

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Upper age limit

35 Years

Sex

All

Total final enrolment

43

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

United Kingdom

England

Study participating centre

Ocular Technology Group International

66 Buckingham Gate

London

England

SW1E 6AU

Sponsor information

Organisation

CooperVision International Limited

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

Individual participant data (IPD) sharing plan**IPD sharing plan summary**

Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Basic results		10/02/2026	12/02/2026	No	No