ISRCTN16940308 https://doi.org/10.1186/ISRCTN16940308

Comparative evaluation of myDay® contact lenses handling

Submission date 05/11/2025	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [X] Record updated in last year
Registration date 05/11/2025	**Overall study status** Completed	
Last Edited 05/11/2025	**Condition category** Eye Diseases	

Plain English summary of protocol

Background and study aims
MyDay® sphere and MyDay® Toric have been shown to performed very well, however, for both contact lens types handling is sometimes reported to be poorer than expected. Handling being an important parameter influencing acceptance by patients it is necessary to gain detailed understanding of handling performance.

The rationale of this study is to characterise the handling performance of MyDay® sphere and MyDay® Toric and measure the effect of lens design/geometry aspect on contact lens handling by comparing the two designs.

Who can participate?
Adults aged 18 to 40 years with previous experience wearing soft contact lenses.

What does the study involve?
The participants will attend the clinic for two study visits and will complete a series of questionnaires during each visit while wearing the study contact lenses . At the first visit the participant will be fitted with the relevant study contact lenses as per the randomization MyDay spherical or MyDay toric. At visit 2 the participant will be fitted with the study contact lenses not fitted at visit 1.

What are the possible benefits and risks of participating?

Participants have the opportunity to try contact lenses to correct their vision. 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?
September 2025 to December 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)
Public

Contact name
Miss Deborah Moore

Contact details
66 Buckingham Gate
London
United Kingdom
SW1E 6AU
+44 2072224224
dmoore@otg.co.uk

Type(s)
Scientific, Principal investigator

Contact name
Prof Michel Guillon

Contact details
66 Buckingham Gate
London
United Kingdom
SW1E 6AU
+44 2072224224
mguillon@otg.co.uk

Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
361079

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
CV25-26 ID25-36

Study information

Scientific Title
Comparative evaluation of MyDay® contact lenses handling

Study objectives
The objective of the study will be to compare the overall ease of handling of MyDay® sphere and MyDay® Toric.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 19/08/2025, Wales REC 3 (Castlebridge 4, 15-19 Cowbridge Road East, Cardiff, CF11 9AB, United Kingdom; +44 2922 940963; Wales.REC3@wales.nhs.uk), ref: 25/WA/0255

Study design
Non-dispensing non interventional prospective double masked within and between group comparisons experimental design involving two clinic visits

Primary study design
Interventional

Study type(s)
Other

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 during each visit while wearing the study contact lenses . At the first visit the participant will be fitted with the relevant study contact lenses as per the randomization MyDay spherical or MyDay toric. At visit 2 the participant will be fitted with the study contact lenses not fitted at visit 1.

The participants will wear each pair of contact lenses for one week, attending a dispense and follow up visit for each contact lens. The randomisation process is through an online tool.

Intervention Type
Device

Phase
Phase IV

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

Primary outcome(s)

Overall ease of handling on a 100-point visual analog scale at baseline/dispense and 7 day follow up visit.

Key secondary outcome(s))
Measured at baseline/dispense and 7 day follow up visit:
1. Measurement of ease of opening the contact lens blister pack on a 100-point visual analog scale
2. Measurement of ease of removing the contact lens from the blister pack on a 100-point visual analog scale
3. Measurement of ease of contact lens insertion on a 100-point visual analog scale
4. Measurement of ease of contact lens removal on a 100-point visual analog scale

Completion date
31/12/2025

Eligibility

Key inclusion criteria
1. Age 18 to 40years
2. Current daily disposable:
Control Contact lens: spherical contact lens wearers
Test contact lens: Toric contact lens wearers
3. Spectacle refraction:
Distance: Sphere: -6.00D to + 2.00D
Astigmatism: 0.00D to -2.25D in each eye
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
40 years

Sex
All

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 recorded during the clinical visit, 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
10/09/2025

Date of final enrolment
31/12/2025

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Ocular Technology Group International
66 Buckingham Gate
London
United Kingdom
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
The datasets generated during and/or analysed during the current study are not expected to be made available.

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes