

Centration of toric contact lenses

Submission date 29/11/2021	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 29/11/2021	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 06/02/2024	Condition category Eye Diseases	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

The quality of vision produced by toric contact lenses depends on how they move when in the eye. The centration of spherical contact lenses is well known in both adult and child/adolescent populations.

In order to develop new designs that stabilise vision in astigmatic patients through the use of toric contact lenses for children and adolescents, it is necessary to use more complex lens designs (such as toric lenses) and the centration of these contact lenses is not well known in child or adolescent populations.

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 wear three different pairs of contact lenses (one spherical and two toric) and have some video recordings of the movement of the contact lenses in their eyes.

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 of the investigator. The study contact lenses are all currently available on the market. The risks to participants are no greater than wearing their own contact lenses. The possible benefit to the participant will be to try different contact lenses with different levels of comfort that 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?

November 2021 to June 2022

Who is funding the study?

CooperVision International Limited (UK)

Who is the main contact?

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Contact information

Type(s)

Public

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Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

Integrated Research Application System (IRAS)

307099

ClinicalTrials.gov (NCT)

Nil known

Protocol serial number

CV21-60 ID21-73, IRAS 307099

Study information

Scientific Title

Toric contact lenses non-dispensing fitting study

Study objectives

The primary efficacy hypotheses to be tested will be that:

1. Contact lens centration in the primary gaze of the test contact lenses is non-inferior to that of the control contact lens
2. Contact lens centration in the reading gaze of the test contact lenses is non-inferior to that of the control contact lens

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved 19/11/2021, London - West London & GTAC Research Ethics Committee (The Old Chapel, Royal Standard Place, Nottingham, NG1 6FS, UK; +44 (0)207 104 8143; westlondon.rec@hra.nhs.uk), REC ref: 21/PR/1482

Study design

Non-dispensing single-centre interventional double-masked randomized crossover trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Astigmatism in myopic children and adolescents

Interventions

Each participant will wear the test and control contact lenses (one pair of each) in a random order for a half-hour period, in which the contact lens fitting video recordings are taken. The videos are then measured post-hoc by a masked investigator.

Participants will be randomised as to the order in which the contact lenses will be fit, in a crossover manner (all participants will wear all of the study contact lenses).

Intervention Type

Device

Phase

Not Applicable

Drug/device/biological/vaccine name(s)

MiSight, MyDay toric, clariti toric

Primary outcome(s)

Contact lens decentration will be reported in mm measured from captures during high-speed high-definition video recording taken after 30 minutes of contact lens wear

Key secondary outcome(s)

1. Rotation of contact lens measured in degrees from captures during high-speed high-definition video recording taken after 30 minutes of contact lens wear
2. Lens handling subjective score measured on a 0-100 point visual analogue scale at contact lens insertion and removal

Completion date

30/06/2022

Eligibility

Key inclusion criteria

1. Age 8 to 15 years
2. Current soft contact lens wearers
3. Parent/guardian and participant have read and understood the Participant Information Sheet
4. Parent/guardian and participant have read, signed and dated the Informed Consent and Assent (when applicable)
5. Best corrected visual acuity of at least 20/25 in each eye
6. Have normal eyes with the exception of the need for visual correction
7. Spectacle refraction: -0.75 to -6.00 D Spherical equivalent, cylinder of at least -0.50 D (with at least 80% of participants with a cylinder of at least -0.75 D)
8. Be willing and able to adhere to the instructions set in the clinical protocol and maintain the appointment schedule

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Child

Lower age limit

8 years

Upper age limit

15 years

Sex

All

Key exclusion criteria

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 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
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

30/11/2021

Date of final enrolment

30/06/2022

Locations

Countries of recruitment

United Kingdom

England

Study participating centre

Optometric Technology Group - International

66 Buckingham Gate

London

United Kingdom

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Sponsor information

Organisation

CooperVision International Limited

Funder(s)

Funder type

Industry

Funder Name

CooperVision International Limited

Results and Publications

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?
Basic results	version 1.0	11/01/2024	06/02/2024	No	No
HRA research summary			28/06/2023	No	No