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Centration of toric contact lenses

Submission date 29/11/2021	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 29/11/2021	**Overall study status** Completed	
Last Edited 06/02/2024	**Condition category** Eye Diseases	

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?
Ned Haigh
nhaigh@otg.co.uk

Contact information

Type(s)
Public

Contact name
Mrs Deborah Moore

Contact details
66 Buckingham Gate
London
United Kingdom
SW1E 6AU
+44 (0)2072224224
dmoore@otg.co.uk

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
307099

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
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

Secondary study design
Randomised cross over trial

Study setting(s)
Other

Study type(s)
Treatment

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 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 measure
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

Secondary outcome measures

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

Overall study start date
24/08/2021

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

Age group
Child

Lower age limit
8 Years

Upper age limit
15 Years

Sex
Both

Target number of participants
25

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
England

United Kingdom

Study participating centre
Optometric Technology Group - International
66 Buckingham Gate
London
United Kingdom
SW1E 6AU

Sponsor information

Organisation
CooperVision International Limited

Sponsor details
Delta Park
Concorde Way
Segensworth North
Fareham
England
United Kingdom

PO15 5RL
+1 (0)855526 6737
MNguyen@coopervision.com

Sponsor type
Industry

Funder(s)

Funder type
Industry

Funder Name
CooperVision International Limited

Results and Publications

Publication and dissemination plan
There are no plans at this stage for publication and dissemination of the study results. However, an abstract for submission at an ophthalmic conference and/or a peer-reviewed publication may be generated.

Intention to publish date
21/12/2022

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