ISRCTN10514147 https://doi.org/10.1186/ISRCTN10514147

Effect of correcting astigmatism on multifocal contact lens performance and acceptance

Submission date
07/06/2021

Recruitment status
No longer recruiting

Registration date
07/06/2021

Overall study status
Completed

Last Edited
29/09/2021

Condition category
Eye Diseases

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Astigmatism means the eye is shaped more like a rugby ball than a football, so light is focused at more than one place in the eye. Astigmatism, along with short sight and long sight, is a common cause of blurry vision. It is usually corrected with glasses or contact lenses. Multifocal contact lens wearers have varying low degrees of astigmatism which affect both visual performance and visual satisfaction. The aim of this study is to measure the effect of astigmatism on visual acuity and vision satisfaction when wearing multifocal contact lenses.

Who can participate?
Adults who are at least 40 years old, have healthy eyes, wear multifocal contact lenses, and have astigmatism from -0.50DC to -1.25DC in both eyes.

What does the study involve?
The study involved a single visit where a series of vision measurements will be carried out while participants wear some contact lenses and spectacles over the top. The whole visit will take about 5 hours in the clinic.

What are the possible benefits and risks of participating?
Participants will use contact lenses that are CE marked. The risk to participants is no greater than wearing their own contact lenses. The risks are further minimised by the fact that the contact lenses will only be worn in the clinic under the supervision of the investigators. The possible benefit to the participant is for them to experience the effect of correcting their astigmatism on their vision.

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?
April 2021 to December 2021

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

Additional identifiers

Integrated Research Application System (IRAS)
300445

Protocol serial number
ID21-32 CV21-37

Study information

Scientific Title
Effect of correcting astigmatism 20 degrees off-axis on multifocal visual performance and acceptance

Study objectives
The hypotheses to be tested will be:
1. Visual performance of multifocal contact lenses with astigmatism corrected 20° off-axis is not inferior to visual performance of multifocal contact lenses without astigmatic correction
2. Visual acceptance of multifocal contact lenses with astigmatism corrected 20° off-axis is not inferior to visual acceptance of multifocal contact lenses without astigmatic correction

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 03/06/2021, London - Westminster Research Ethics Committee (The Old Chapel, Rotal Standard Place, Nottingham, NG1 6FS, UK; 44(0)207 104 8388; westminster.rec@hra.nhs.uk), REC ref: 21/PR/0749

Primary study design
Interventional

Study design
Single-centre interventional double-masked randomized trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Vision correction of astigmatic presbyopes using multifocal contact lenses

Interventions
Multifocal contact lenses are used in wearers with various levels of astigmatism. It is important to understand the effect of astigmatism on visual performance of multifocal contact lenses. In this study the researchers will measure visual performance and visual satisfaction for patients while adding an astigmatic correction, compared to when there is no astigmatic correction.

Randomisation is computer-generated for the order of testing the different corrections. There is only one intervention arm as it is a cross over study. The contact lenses worn by participants will be MyDay Multifocal contact lenses worn as per their CE marking. Participants will also wear two different sets of spectacles in a random order to provide an over-correction. One set of spectacles will be plano, another set of spectacles will provide an astigmatic correction. Each correction is only worn for approx. 2 hours in the clinic.

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
MyDay Multifocal

Primary outcome(s)
1. Overall binocular visual acuity measured in logMAR after approximately 1 hour of contact lens wear
2. Overall binocular visual satisfaction measured by 100-point visual analogue scale (VAS) after approximately 1 hour of contact lens wear

Key secondary outcome(s)
1. Individual monocular and binocular timed visual acuity measured in logmAR after approximately 1 hour of contact lens wear
2. Overall monocular timed visual acuity in the dominant eye measured in logMAR after approximately 1 hour of contact lens wear
3. Overall monocular timed visual acuity in the non-dominant eye measured in logMAR after approximately 1 hour of contact lens wear
4. Individual visual satisfaction at distance, intermediate, and near, measured by 100-point VAS after approximately 1 hour of contact lens wear

Completion date

31/12/2021

Eligibility

Key inclusion criteria
1. 40 or more years of age
2. Have read and understood the Participant Information Sheet in English
3. Have read, signed and dated the Informed Consent
4. Best corrected visual acuity of at least 20/25 in each eye
5. Have normal eyes with the exception of the need for visual correction
6. Current multifocal contact lens wearer
7. Spectacle refraction:
Distance: Sphere: -6.00 D to + 4.00 DS
Astigmatism: -0.50 DC to -1.25 DC in both eyes
Near Addition: +0.75 D to +2.50 D
8. Willing and able to adhere to the instructions set in the clinical protocol and maintain the appointment schedule

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Total final enrolment
16

Key exclusion criteria
1. Ocular anterior segment infection, inflammation, abnormality, or active disease that would contraindicate contact lens wear
2. Use of systemic or ocular medications 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. Any moderate or severe ocular condition observed during the slit-lamp examination at the enrolment visit
5. History of herpetic keratitis, ocular surgery or irregular cornea
6. Known pregnancy or lactation during the study period
7. Enrolment of the investigator or his/her staff, 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
10/06/2021

Date of final enrolment
31/10/2021

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Optometric Technology Group Limited
Lower Ground Floor
66 Buckingham Gate
London
United Kingdom
SW1E 6AU

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 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		28/09/2021	29/09/2021	No	No
HRA research summary			28/06/2023	No	No