ISRCTN47409350 https://doi.org/10.1186/ISRCTN47409350

The effect of astigmatism on multifocal contact lens visual performance

Submission date	Recruitment status	[_] Prospectively registered
10/12/2020	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
27/01/2021	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
29/01/2021	Eye Diseases	

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, who have healthy eyes and wear multifocal contact lenses and have astigmatism from -0.50 D in both eyes or -0.75 DC to -1.25 DC in one eye.

What does the study involve?
The study involves a single visit where a series of vision measurements will be carried out. Participants wear MyDay Multifocal and Proclear 1Day Multifocal contact lenses for about 2 hours each in the clinic.

What are the possible benefits and risks of participating?
The participants are current multifocal contact lens wearers and they will use multifocal contact lenses which are CE marked. The risk to the 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 from and how long is it expected to run for?
May 2019 to December 2019

Who is funding the study?
CooperVision Inc. (USA)

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 (0)207 222 4224
dmoore@otg.co.uk

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
271679

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
CV19-64 ID19-38, IRAS 271679

Study information

Scientific Title
The effect of astigmatism on multifocal contact lens visual performance - a pilot study

Study objectives
The study is a pilot feasibility study so formal hypothesis testing is not possible. Multifocal contact lenses are used in patients with astigmatism up to 0.75DC as per their CE marking. The rationale for the study is to measure the effect of astigmatism of the visual performance on multifocal contact lenses.

Ethics approval required
Old ethics approval format

Ethics approval(s)

Approved 25/09/2019, West Midlands - Solihull Research Ethics Committee (The Old Chapel, Royal Standard Place, Nottingham, NG1 6FS, UK; +44 (0)207 104 8191; NRESCommittee.WestMidlands-Solihull@nhs.net), REC ref: 19/WM/0270

Study design
Prospective randomized double-masked single-group crossover study

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 the contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Presbyopia vision correction 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 with different levels of astigmatism.

Randomisation is computer-generated for the order of testing the different corrections (MyDay Multifocal and Proclear 1Day Multifocal). There is only one intervention arm as it is a cross over study. 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, Proclear 1Day Multifocal

Primary outcome measure
Visual performance (overall binocular and monocular) measured using LogMar charts at approximately 30 mins after the contact lenses are inserted

Secondary outcome measures

Visual satisfaction (overall binocular and monocular) measured using LogMar charts at approximately 30 mins after the contact lens are inserted

Overall study start date
01/05/2019

Completion date
31/12/2019

Eligibility

Key inclusion criteria
1. At least 40 years old
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: -6.00DS to + 4.00DS Astigmatism: a. -0.50 DC in both eyes or b. -0.75 DC to -1.25 DC in one eye
Near Addition: +0.75 D to +2.50 D
8. Be willing and able to adhere to the instructions set in the clinical protocol and maintain the appointment schedule

Participant type(s)
Healthy volunteer

Age group
Adult

Sex
Both

Target number of participants
45

Total final enrolment
15

Key exclusion criteria
1. Ocular anterior segment infection, inflammation, abnormality, or active disease that would contraindicate contact lens wear
2. Newly prescribed use of some 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
01/09/2019

Date of final enrolment
31/12/2019

Locations

Countries of recruitment
England

United Kingdom

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

Sponsor information

Organisation
CooperVision (United States)

Sponsor details
6150 Stoneridge Mall Road
Pleasanton
United States of America
94588
+1 (0)925 251 6682
plazon@coopervision.com

Sponsor type
Industry

Website
http://coopervision.com

Funder(s)

Funder type
Industry

Funder Name
CooperVision Inc. (USA)

Results and Publications

Publication and dissemination plan
There are no specific plans for publication or dissemination of the study results.

Intention to publish date
31/12/2020

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		28/01/2021	29/01/2021	No	No
HRA research summary			28/06/2023	No	No