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Validation of CV multifocal daily disposable contact lenses performance in a multisite study

Submission date
21/01/2019

Recruitment status
No longer recruiting

Registration date
24/01/2019

Overall study status
Completed

Last Edited
22/10/2020

Condition category
Eye Diseases

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

Plain English summary of protocol

Background and study aims
To test the performance of CV Multifocal (MF) contact lens (CL) in a real world setting, the lenses need to be worn by wearers representing different level of near vision needs and compared with a MF CL that is widely used on the market (control). The aims of this study are to compare CV MF CL with a control for overall satisfaction, visual performance, and ease of fit.

Who can participate?
Adults who are at least 40 years old, who have healthy eyes and wear contact lenses

What does the study involve?
There are up to four study visits over a three-week period. The first visit is screening and enrollment. Following that at the second visit, participants are fitted with both study lenses according to the fitting guide and the investigator assesses the lens fit and measures vision with the lenses. Participants are asked to complete a short questionnaire. The first MF CL is dispensed (test or control allocated by chance) and worn on a daily disposable basis for a week. At the third visit, the first lens type is evaluated and then the second lens type is dispensed. The same routine as the first lens type is followed for the second type of MF CL. At the fourth visit, the second lens type is evaluated and then the participant leaves the study.

What are the possible benefits and risks of participating?
There might not be direct benefits to the participants. Participants will receive an examination of their eyes and may have the opportunity to try different types of soft MF CL at no cost. Due to the nature and duration of the study, the risks of participating are considered minimal. All the assessments are safe, and none present any increased risk compared with routine assessment. Participants already wear contact lenses. The risks of taking part in the study are no greater than those associated with wearing their own contact lenses. The study lenses are approved marketed daily disposable lenses and there will be no lens care system used.

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?
August 2018 to August 2019

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

Who is the main contact?
Ms Trisha Patel

Contact information

Type(s)
Public

Contact name
Ms Trisha Patel

Contact details
66 Buckingham Gate
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Additional identifiers

Protocol serial number
CV 18-56/OTG-i ID18-43

Study information

Scientific Title
Clinical validation multisite study of CV multifocal contact lenses

Study objectives
The primary hypothesis to be tested will be that overall visual satisfaction of CV MF is non-inferior to that of control lens; overall satisfaction will be measured in term of overall visual acceptance.

Ethics approval required
Old ethics approval format

Ethics approval(s)
North West - Greater Manchester West Research Ethics Committee, Barlow House, 3rd Floor, 4 Minshull Street Manchester. M1 3DZ, Tel: +44 (0)207 104 8021, Email: nrescommittee.northwest-gmwest@nhs.net, 24/10/2018, REC Ref: 18/NW/0705

Study design
Prospective one-week dispensing randomized two-way cross over subject masked study

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Presbyopia, multi-focal contact lenses, vision

Interventions
It is important that the multifocal contact lenses prescribed for an invididual perform as intended and provide the wearers with good overall satisfaction, visual performance and the prescribing routine was simple and easy to follow. In this study the overall clinical behavior of CV MF contact lens is compared to that the most commonly contact lens of the same type to identify relative subjective benefits. Participants will use both test (CV MF) and control (1-DAY ACUVUE® MOIST Multifocal 1DAVM) in a randomized sequence for one week each. Measurements will include distance and near visual acuity, lens fitting characteristics and subjective responses using questionnaires.

Intervention Type
Device

Primary outcome(s)
Overall subjective binocular visual satisfaction score on a 100-point Visual Analog Scale (VAS) at dispensing and after one week wear

Key secondary outcome(s))
1. Binocular visual acuity measurements using LogMAR charts after 1 week wear
2. The number of contact lenses needed per eye to determine the contact lens to be dispensed at dispensing visit

Completion date
31/08/2019

Eligibility

Key inclusion criteria
There are no requirements as to participant race, gender or occupation. In order to be enrolled, each participant shall meet the following criteria:
1. At least 40 years old;
2. Have read and understood the Participant Information Sheet
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: -6.00D to + 4.00D
Astigmatism: 0.00D to -0.75D
Near Addition: +0.75D to +2.50D in three groups:
Emerging Presbyopes: +0.75D to +1.25D

Established Presbyopes: +1.50D and +1.75D
Advanced presbyopes: +2.00D to +2.50D
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

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
The following are specific criteria that exclude a candidate from enrolment in this study:
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
12/11/2018

Date of final enrolment
31/07/2019

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 Inc. (USA)

Funder(s)

Funder type
Industry

Funder Name
CooperVision, Inc.

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			22/10/2020	No	No
HRA research summary			28/06/2023	No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes