ISRCTN50917346 https://doi.org/10.1186/ISRCTN50917346

Vision comparison of two multifocal contact lenses

Submission date	Recruitment status	[X] Prospectively registered
12/06/2020	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
15/06/2020	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
18/02/2021	Eye Diseases	

Plain English summary of protocol

Background and study aims
As part of assessing the performance and acceptance of new multifocal contact lenses it is standard to compare them to other contact lenses on the market. The aim of this study is to determine the acceptance and the vision performance of the new Invigor contact lenses compared with 1-Day Acuvue® Moist contact lenses.

Who can participate?
Adults who are at least 40 years old and who have healthy eyes and are current multifocal contact lens wearers.

What does the study involve?
Each participant attends the clinic on three occasions. At the first visit after being screened and enrolled in the study, their eyes are examined and they are fitted and dispensed with one of the two study contact lenses (which lens type is used first is randomly determined like tossing a coin). The second visit takes place 1 week after the first, during that visit the contact lens which the participant wore are assessed. Then, the participant is fitted and dispensed with the other contact lens type, which they wear for 1 week. At the third and final visit, the contact lenses that have been worn are assessed and the participant is discharged from the study.

What are the possible benefits and risks of participating?
The participants will have the opportunity to try two different types of multifocal contact lenses which they may prefer to their own multifocal contact lenses and at a later date may decide to opt for these lenses. The two contact lens types are CE marked and therefore the risks are no different to them wearing their own contact lenses.

Where is the study run from?
Ocular Technology Group - International Research Clinic (UK)

When is the study starting from and how long is it expected to run for?
April 2020 to December 2020

Who is funding the study?
CooperVision Inc (USA)

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)
283312

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
CV20-44, IRAS 283312

Study information

Scientific Title
Clinical performance and acceptance of Invigor multifocal vs 1-day Acuvue® moist multifocal contact lenses

Study objectives
The performance of the new Invigor contact lens is not inferior to 1-day Acuvue® moist multifocal contact lens.

Ethics approval required

Old ethics approval format

Ethics approval(s)
Approved 19/05/2020, East of England - Cambridge Central Research Ethics Committee (Royal Standard Place, Nottingham, NG1 6FS, UK; +44 (0)207 104 8388; cambridgecentral.rec.hra.nhs.uk), REC ref: 20/EE/0119

Study design
Single-centre prospective randomised (testing order) double-masked cross over study

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Presbyopia vision correction using multifocal contact lenses

Interventions
Multifocal contact lenses are prescribed to provide wearers with good vision satisfaction and visual performance using the manufactures prescribing routine. It is important to compare this feature for a new contact lens with established contact lenses.

The study is a cross over study, the participants wear both contact lens types, the randomisation is limited to the order of testing, the randomisation process is a computer-based randomisation selection process. The participant will wear each contact lens (Invigor multifocal or 1-day Acuvue® moist multifocal contact lenses) for a week and at the end of the week visual satisfaction will be recorded using 100 point analogue scale for different vision condition eg. driving, computer use, reading. The visual performance will be measured using computerised logMAR charts at long distance, 4 metres, and near 40 cm.

Intervention Type
Device

Phase
Not Applicable

Primary outcome(s)
Overall vision satisfaction recorded on a 100-point vision analogue scale at 1 week

Key secondary outcome(s))
1. Overall visual performance measured using LogMar visual acuity at 1 week
2. Number of contact lenses needed at the dispensing visit to determine the contact lens power to use during the study

Completion date
30/03/2021

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: Emerging Presbyopes: +0.75D to +1.25D
Established Presbyopes: +1.50D & +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
To be eligible as a participant, each candidate shall be free of any ocular or medical condition that may affect the results of this study. 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
01/07/2020

Date of final enrolment

30/11/2020

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 (United States)

Funder(s)

Funder type
Industry

Funder Name
CooperVision Inc. (USA)

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	28/01/2021	18/02/2021	No	No
HRA research summary		28/06/2023	No	No