

Vision comparison of two multifocal contact lenses

Submission date 12/06/2020	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 15/06/2020	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 18/02/2021	Condition category Eye Diseases	<input type="checkbox"/> Individual participant data

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?
Deborah Moore
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Contact information

Type(s)
Public

Contact name
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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
283312

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
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

Secondary study design

Cluster randomised 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

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 measure

Overall vision satisfaction recorded on a 100-point vision analogue scale at 1 week

Secondary outcome measures

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

Overall study start date

01/04/2020

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

Age group

Adult

Sex

Both

Target number of participants

150

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

England

United Kingdom

Study participating centre

Ocular Technology Group - International

66 Buckingham Gate

London

United Kingdom

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Sponsor information

Organisation

CooperVision (United States)

Sponsor details

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Sponsor type

Industry

Website

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Funder(s)

Funder type

Industry

Funder Name

CooperVision Inc. (USA)

Results and Publications

Publication and dissemination plan

The protocol and statistical analysis plan are confidential documents from the sponsor and have been reviewed by the Ethics Committee under usual confidentiality conditions. There are no specific plans for publication or 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

31/12/2021

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