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Effect of multifocal contact lenses on binocular vision

Submission date	Recruitment status	[X] Prospectively registered
18/10/2021	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
18/10/2021	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
12/04/2022	Eye Diseases	

Plain English summary of protocol

Background and study aims
Part of the development of new multifocal contact lens designs involves comparing them with other marketed contact lenses and also monovision contact lenses to ensure there is no loss of binocular vision. Binocular vision refers to how the eyes work together to produce a three-dimensional perception of the world. This study aims to compare control multifocal contact lenses versus test multifocal contact lenses and a control monovision contact lens compared to the test multifocal contact lenses.

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

What does the study involve?
The study involves two non-dispensing visits where a series of vision measurements will be carried out while participants wear different pairs of contact lenses for 1 hour each. Each visit will take about 6 hours in the clinic and they will be 2-14 days apart.

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 different types of contact lenses that they may not have tried before.

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?
July 2021 to December 2021

Who is funding the study?
CooperVision International Limited (UK)

Who is the main contact?
Deborah Moore
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Contact information

Type(s)
Public

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
305799

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
CV21-69 ID21-69, IRAS 305799

Study information

Scientific Title
Quantification of binocular summation of multifocal and monovision contact lenses

Study objectives
1. Improvement in overall binocular visual acuity from monocular acuity is non-inferior to that achieved with the test multifocal contact lenses is non-inferior to that with the control multifocal contact lenses
2. The improvement in overall binocular visual acuity from overall binocular visual acuity from monocular acuity with the test multifocal contact lenses is superior to that achieved with the control monovision contact lenses

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 14/10/2021, North of Scotland Research Ethics Committee (Summerfield House, 2 Eday Road, Aberdeen, AB15 6RE, UK; +44 (0)1224 558458; gram.nosres@nhs.scot), REC ref: 21 /NS/0131

Study design
Single-centre interventional double-masked randomized trial

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 contact details to request a participant information sheet.

Health condition(s) or problem(s) studied
Presbyopia

Interventions
In this study the researchers will measure the visual performance and binocular performance of various control multifocal contact lenses compared to a test multifocal contact lens, and a control monovision contact lens to a test multifocal contact lens.

The study involves two non-dispensing visits where a series of vision measurements will be carried out while participants are randomised using randomization.com to wear different pairs of contact lenses (MyDay Multifocal, MyDay Spherical, Biofinity Multifocal, Acuvue Moist Multifocal) for 1 hour each. Each visit will take about 6 hours in the clinic and they will be 2-14 days apart.

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
MyDay Multifocal, MyDay Spherical, Biofinity Multifocal, Acuvue Moist Multifocal

Primary outcome measure
1. Overall binocular timed visual acuity measured in logMAR after approximately 30 minutes of contact lens wear

2. Overall monocular timed visual acuity measured in logMAR after approximately 30 minutes of contact lens wear
3. Binocular vision measured in arcseconds after approximately 1 hour of contact lens wear

Secondary outcome measures
There are no secondary outcome measures

Overall study start date
18/07/2021

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. Current multifocal contact lens wearer
5. Spectacle refraction:
Distance: Sphere: -6.00D to + 4.00DS
Astigmatism: -0.00DC to -0.75DC in each eye
Near Addition: +0.75D to +2.50D
6. Best corrected visual acuity of at least 20/25 in each eye
7. Have normal eyes with the exception of the need for visual correction
8. Be willing and able to adhere to the instructions set in the clinical protocol and maintain the appointment schedule

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
30

Total final enrolment
21

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
18/10/2021

Date of final enrolment
01/12/2021

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Optometric Technology Group Limited
66 Buckingham Gate
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Sponsor information

Organisation
CooperVision International Limited

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Sponsor type
Industry

Website
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Funder(s)

Funder type
Industry

Funder Name
CooperVision

Results and Publications

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

Intention to publish date

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		31/01/2022	12/04/2022	No	No
HRA research summary			28/06/2023	No	No