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Multifocal contact lenses fitting methods comparison

Submission date	Recruitment status	[_] Prospectively registered
11/10/2022	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
26/10/2022	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
02/06/2023	Eye Diseases	

Plain English summary of protocol

Background and study aims
Presbyopia is the gradual loss of the eyes' ability to focus on nearby objects. It's a natural, often annoying part of ageing. Presbyopia usually becomes noticeable in the early to mid-40s and continues to worsen until around age 65.
Multifocal contact lenses (contact lenses that correct both distance and near vision for people who need reading glasses) come in very different designs some giving better vision at near or at distance. This study investigates two methods of fitting a marketed multifocal contact lens and compares the vision satisfaction and visual performance achieved with each method.

Who can participate?
Adults aged 40 years old and over who have healthy eyes and are current multifocal contact lens wearers

What does the study involve?
Particiants will attend three study visits over a two-week period:
Visit 1: Screening/Enrolment/Fitting and First Lens Dispensing
Visit 2 (7 +2/-0 days from Visit 1): First Lens follow-up visit, Second Lens Dispensing
Visit 3 (7 +2/-0 days from Visit 2): Second lens follow-up visit/Exit

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 pair is used first is randomly determined like tossing a coin). The second visit takes place one week after the first, during that visit the contact lenses which the participant wore are assessed. Then, the participant is fitted and dispensed with the other contact lens pair, which they wear for one 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 study contact lenses are CE marked and therefore the risks to participants 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 and how long is it expected to run for?
August 2022 to June 2023

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

Who is the main contact?
Deborah Moore (UK)
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Contact information

Type(s)
Public

Contact name
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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
319324

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
CV22-49, IRAS 319324

Study information

Scientific Title
Biofinity® Multifocal contact lenses fitting methods comparison

Acronym

Claret

Study objectives
The primary hypotheses tested are:
1. Overall vision satisfaction with the study contact lens after one week of wear is non-inferior for the test contact lens (distance near balanced correction [non-dominant eye Near Design) to that of the control contact lens (distance favoured correction)
2. Overall preference between the study contact lens is non-inferior for the test contact lens (distance near balanced correction) to that of the control contact lens (distance favoured correction) at the completion of the study

The secondary hypotheses tested are:
1. Overall binocular visual performance with the study contact lens after one week of wear is non-inferior for the test contact lens (distance near balanced correction) to that of the control contact lens (distance favoured correction)
2. The number of contact lenses to determine the contact lens power to dispense the study contact lens is non-inferior for the test contact lens (distance near balanced correction) to that of the control contact lens (distance favoured correction)

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 04/10/2022, London - Bloomsbury Research Ethics Committee (HRA RES Centre Manchester, 3rd Floor Barlow House, 4 Minshull Street, Manchester, M1 3DZ, UK; telephone not provided; bloomsbury.rec@hra.nhs.uk), ref: 22/PR/1137

Study design
Single-centre non-interventional prospective double-masked randomized crossover trial

Primary study design
Other

Secondary study design

Study setting(s)
Other

Study type(s)
Quality of life

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
Multifocal contact lenses are prescribed to provide wearers with good vision satisfaction and visual performance using the manufacturer's prescribing routine. This study will investigate two

methods of fitting a marketed multifocal contact lens and compare the vision satisfaction and visual performance achieved with each method.

The study is a crossover design so all participants will wear both methods of fitting the contact lenses. Randomisation is limited to the order of testing and is a computer-based randomisation selection process. The participant will wear each contact lens for 1 week and at the end of the week visual satisfaction will be recorded using a 100-point analogue scale for different vision conditions, distance, intermediate and near vision. The visual performance will be measured using computerised logMAR charts at 4m, 67cm and near 40cm.

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Biofinity® Multifocal contact lenses

Primary outcome measure
1. Overall binocular vision satisfaction measured using a 100-point visual analogue scale (VAS) after one week of wear
2 Overall preference measured using a forced choice scale at the completion of the study

Secondary outcome measures
1. Mean binocular visual performance measured using timed logMAR mean visual acuity after one week of wear
2. Number of contact lenses needed per participant to determine the contact lens pair to be dispensed

Overall study start date
01/08/2022

Completion date
15/06/2023

Eligibility

Key inclusion criteria
1. Aged 40 years old and over
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:
7.1. Distance:
7.1.1. Sphere -6.00D to + 4.00D
7.2.1. Astigmatism 0.00D to -0.75D
7.2. Near Addition:

7.2.1. Established Presbyopes: +1.50D and +1.75D
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

Lower age limit
40 Years

Sex
Both

Target number of participants
25

Total final enrolment
25

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
10/10/2022

Date of final enrolment
01/05/2023

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Ocular Technology Group - international (OTG-i)
66 Buckingham Gate
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Sponsor information

Organisation
CooperVision International Limited

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Sponsor type
Industry

Website
https://www.coopervision.com

Funder(s)

Funder type
Industry

Funder Name
CooperVision International Limited

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 the 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
01/05/2024

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	version 1.0	23/05/2023	02/06/2023	No	No
HRA research summary			28/06/2023	No	No