ISRCTN14349364 https://doi.org/10.1186/ISRCTN14349364

Performance and acceptance of multifocal contact lenses

Submission date
17/02/2021

Recruitment status
No longer recruiting

Registration date
17/02/2021

Overall study status
Completed

Last Edited
20/07/2021

Condition category
Eye Diseases

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

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. In order to improve this type of contact lenses it is important to compare how well different designs are tolerated by patient and correct vision.
The study compares the level of vision satisfaction and the visual acuity achieved by two different contact lenses designs currently available.

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 pair 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 lenses which the participant wore are assessed. Then, the participant is fitted and dispensed with the other contact lens pair, 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?
September 2020 to June 2021

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

Who is the main contact?
Deborah Moore
dmoore@otg.co.uk

Contact information

Type(s)
Public

Contact name
Miss Deborah Moore

Contact details
66 Buckingham Gate
London
United Kingdom
SW1E 6AU
+44 (0)2072224224
dmoore@otg.co.uk

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
293763

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
CV20-81 ID20-76, IRAS 293763

Study information

Scientific Title
Performance and acceptance of biofinity multifocal contact lenses vs. multifocal pluto contact lenses

Study objectives
The primary hypothesis to be tested will be that overall vision satisfaction of the test contact lenses is non-inferior to that of the control contact lenses after 1 week of wear for:

1. Overall vision satisfaction
2. Visual performance
3. The number of contact lenses that are needed to arrive at the final contact lens to dispense

The secondary hypothesis to be tested will be that:
1. Overall binocular visual performance of the test system is non-inferior to that of the control system after one week of wear
2. The number of contact lenses to determine the contact lenses to dispense for the test system is non-inferior (does not require more contact lenses to be trialled) than for the control system at dispensing

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 11/02/2021, East of England - Cambridgeshire and Hertfordshire Research Ethics Committee (The Old Chapel, Royal Standard Place, Nottingham, NG1 6FS, UK; +44 (0) 2071048096; cambsandherts.rec@hra.nhs.uk), REC ref: 21/EE/0030

Study design
Single-centre non-interventional prospective double-masked randomized crossover 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
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 (Biofinity and Pluto daily disposable multifocal contact lenses), 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 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 long distance, 4 metres, and near 40 cm.

Intervention Type
Device

Phase
Not Applicable

Primary outcome measure
Overall vision satisfaction measured on a 110-point analog scale after 1 week of wear

Secondary outcome measures
1. Overall visual performance measured by LogMAR visual acuity after 1 week of wear
2. The number of contact lenses tested to determine the contact lens power to be used during the study

Overall study start date
28/09/2020

Completion date
01/06/2021

Eligibility

Key inclusion criteria
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 in English
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)
Patient

Age group
Mixed

Sex

Both

Target number of participants
60

Total final enrolment
45

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
22/02/2021

Date of final enrolment
10/05/2021

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Ocular Technology Group - International
66 Buckingham Gate
London
United Kingdom
SW1E 6AU

Sponsor information

Organisation

CooperVision International Limited

Sponsor details
Delta Park
Concorde Way
Segensworth North
Fareham
United Kingdom
PO15 5RL
+1 (0)925 2516615
tdoan@coopervision.com

Sponsor type
Industry

Website
https://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
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	version v0.1		20/07/2021	No	No
HRA research summary			28/06/2023	No	No