ISRCTN13286992 https://doi.org/10.1186/ISRCTN13286992

Refitting Biofinity® Multifocal contact lenses wearers with MyDay® Multifocal contact lenses

Submission date
02/02/2024

Recruitment status
No longer recruiting

Registration date
09/02/2024

Overall study status
Completed

Last Edited
14/11/2024

Condition category
Eye Diseases

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

Plain English summary of protocol

Background and study aims
Soft contact lenses to correct presbyopia (loss of reading vision due to age) are made of different materials which may affect the ease of handling. Contact lenses to correct presbyopia also have different optical designs that may produce different vision results. The aim of this study is to compare the ease of handling and vision acuity of Biofinity® multifocal contact lenses and MyDay® multifocal contact lenses, two successful contact lenses to correct presbyopia currently CE marked and on the UK market.

Who can participate?
Adults aged 40 years and older who are current soft contact lens wearers and have presbyopia

What does the study involve?
Participants will attend the clinic on three separate occasions about 2 weeks apart. Two different contact lenses will be dispensed at the first two visits and to be worn for approximately two weeks. At visits 2 and 3 the ease of handling and visual acuity will be assessed by the investigators.

What are the possible benefits and risks of participating?
Participants have the opportunity to try contact lenses to correct presbyopia. Any contact lens wear comes at the risk of corneal infection, but the incidence rate is very low

Where is the study run from?
Ocular Technology Group - International (OTG-i) (UK)

When is the study starting and how long is it expected to run for?
November 2023 to June 2024

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

Who is the main contact?
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Contact information

Type(s)
Public

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Additional identifiers

ClinicalTrials.gov (NCT)
NCT06328660

Integrated Research Application System (IRAS)
338011

Protocol serial number
EX-MKTG-155 ID23-62

Study information

Scientific Title
Refitting Biofinity® Multifocal contact lenses wearers with MyDay® Multifocal contact lenses

Study objectives
The primary hypothesis to be tested will be that the handling of MyDay® multifocal contact lenses will not be inferior to the handling of Biofinity® multifocal contact lenses.

The secondary hypothesis to be tested will be that the visual acuity of MyDay® multifocal contact lenses will not be inferior to the mean logMAR visual acuity of Biofinity® multifocal contact lenses.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 29/12/2023, North East York Research Ethics Committee (2 Redman Place, Stratford London, E20 1JQ, United Kingdom; +44 (0)207 104 8079; york.rec@hra.nhs.uk), ref: 23/NE/0239

Primary study design
Interventional

Study design
Interventional prospective open-label sequential study

Study type(s)
Other

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

Interventions
The participant will wear in turn the two study contact lenses (Biofinity® Multifocal and MyDay® Multifocal) for 2 weeks as their vision correction modality. The participants will attend the clinic for three study visits about 2 weeks apart.

Intervention Type
Device

Phase
Phase IV

Drug/device/biological/vaccine name(s)
Biofinity® multifocal, MyDay® multifocal

Primary outcome(s)
The ease of handling over the week preceding the follow-up visit, measured using subjective ratings and satisfaction questionnaires during the follow-up visits

Key secondary outcome(s)
Visual acuity, measured using logMAR visual acuity recorded during the follow-up visits

Completion date
14/06/2024

Eligibility

Key inclusion criteria

1. Age 40 years and older
2. Current multifocal contact lens wearer (other than MyDay® multifocal but can include Biofinity® multifocal)
3. Spectacle refraction:
Distance: Sphere: -6.00D to + 4.00D
Astigmatism: 0.00D to -0.75D
Near Addition: +0.75D to +2.50D
4. Best corrected visual acuity of at least 20/25 in each eye
5. The prospective participants will be given a Participant Information Sheet to read and an Informed Consent Form to sign prior to any evaluation.

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
40 Years

Sex
All

Key exclusion criteria
1. Acute and subacute inflammation or infection of the anterior chamber of the eye
2. Any eye disease, injury or abnormality that affects the cornea, conjunctiva or eyelids that would contraindicate contact lens wear
3. Corneal hypoesthesia (reduced corneal sensitivity), if not aphakic
4. Severe insufficiency of lacrimal secretion (dry eyes)
5. Any systemic disease that may affect the eye or may be exaggerated by wearing contact lenses (e.g. acne and eczema)
6. Allergic reactions of ocular surfaces or adnexa that may be induced or exaggerated by wearing contact lenses or use of contact lens solutions
7. Any active corneal infection (bacterial, fungal, protozoal or viral)
8. Newly prescribed (within the past 30 days) use of some systemic medications (such as antihistamines, decongestants, diuretics, muscle relaxants, tranquilizers, stimulants, anti-depressants, anti-psychotics, oral contraceptives) or new prescription eyedrops which is not rewetting/lubricating eyedrops for which contact lens wear could be contraindicated as determined by the investigator
9. Monocular participants (only one eye with functional vision) or participants fit with only one contact lens
10. Subjects with slit lamp findings greater than grade 1 (e.g. edema, infiltrates, corneal neovascularization, corneal staining, tarsal abnormalities, conjunctival, anterior segment inflammation) as per ISO 11980, any previous history or signs of a contact lens related corneal inflammatory event (past corneal ulcers), or any other ocular abnormality that may contraindicate contact lens wear at the enrolment visit;
11. History of corneal refractive surgery
12. Enrolment of the family members of the investigator, family members of the investigator’s

staff, or individuals living in the households of these individuals
13. Current wearer of the test contact lens MyDay® multifocal contact lens

Date of first enrolment
06/02/2024

Date of final enrolment
26/04/2024

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Ocular Technology Group International Ltd
66 Buckingham Gate
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Sponsor information

Organisation
Coopervision International Limited

Funder(s)

Funder type
Industry

Funder Name
CooperVision

Alternative Name(s)
CooperVision, Inc., CooperVision Inc, CooperVision Inc., CooperVision, Inc

Funding Body Type
Government organisation

Funding Body Subtype
For-profit companies (industry)

Location
United States of America

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	version 0.2	28/10/2024	14/11/2024	No	No