

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

Submission date 02/02/2024	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 09/02/2024	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 14/11/2024	Condition category Eye Diseases	<input type="checkbox"/> 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

EudraCT/CTIS number

Nil known

IRAS number

338011

ClinicalTrials.gov number

NCT06328660

Secondary identifying numbers

EX-MKTG-155 ID23-62, IRAS 338011

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

Study design

Interventional prospective open-label sequential study

Primary study design

Interventional

Secondary study design

Non randomised study

Study setting(s)

Other

Study type(s)

Other

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

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

Pharmaceutical study type(s)

Not Applicable

Phase

Phase IV

Drug/device/biological/vaccine name(s)

Biofinity® multifocal, MyDay® multifocal

Primary outcome measure

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

Secondary outcome measures

Visual acuity, measured using logMAR visual acuity recorded during the follow-up visits

Overall study start date

01/11/2023

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

Age group

Adult

Lower age limit

40 Years

Sex

Both

Target number of participants

70

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

England

United Kingdom

Study participating centre

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Sponsor information

Organisation

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Sponsor type

Industry

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**Publication and dissemination plan**

There are no plans at this stage for publication or dissemination.

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