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Multifocal contact lens performance and acceptance

Submission date	Recruitment status	[_] Prospectively registered
10/12/2020	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
28/01/2021	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
28/01/2021	Eye Diseases	

Plain English summary of protocol

Background and study aims
Contact lenses are small prescription lenses, worn in "contact" with the eye. They are designed to correct eyesight and maintain eye health.
The aim of this study is to determine the acceptance and the vision performance of Miru multifocal contact lenses compared with 1-Day Acuvue® Moist contact lenses.

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 type 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 lens which the participant wore are assessed. Then, the participant is fitted and dispensed with the other contact lens type, 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?
August 2019 to December 2020

Who is funding the study?
CooperVision Inc (USA)

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
274407

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
CV19-84 ID19-50, IRAS 274407

Study information

Scientific Title
Miru multifocal contact lens performance and acceptance assessment

Study objectives
The overall visual satisfaction and binocular visual performance with Miru multifocal will not be inferior to that of 1 DAY ACUVUE Moist multifocal.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 17/12/2019, North West - Preston Research Ethics Committee (Barlow House 3rd Floor, 4 Minshull Street, Manchester, M1 3DZ, UK; +44 (0)207 104 8056; preston.rec@hra.nhs.uk), ref: 19/NW/00713

Study design
Prospective double-masked randomized cross over pilot feasibility study

Primary study design
Interventional

Secondary study design
Randomised cross over trial

Study setting(s)
Other

Study type(s)
Other

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet.

Health condition(s) or problem(s) studied
Presbyopia vision correction using multifocal contact lenses

Interventions
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 (chosen at random). The randomisation process is 1:1 randomisation using a computerised program.
The second visit takes place 1 week after the first, during that visit the contact lens which the participant wore are assessed. Then, the participant is fitted and dispensed with the other contact lens type, 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.

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Miru multifocal contact lenses, 1 DAY ACUVUE Moist multifocal contact lenses

Primary outcome measure
Overall binocular vision satisfaction measured on a 100 point Visual Analogue scale at the end of the wearing period 7 +2/-1 days of wear.

Secondary outcome measures
Overall binocular visual performance measured as the mean of the distance and near LogMar visual acuity after 7 +2/-1 days of wear.

Overall study start date
01/08/2019

Completion date
14/12/2020

Eligibility

Key inclusion 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 soft 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
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

Sex
Both

Target number of participants
45

Total final enrolment
27

Key exclusion criteria
1. Currently wearing study contact lenses
2. Ocular anterior segment infection, inflammation, abnormality, or active disease that would contraindicate contact lens wear
3. Newly prescribed use of some systemic or ocular medications for which contact lens wear could be contraindicated as determined by the investigator
4. Monocular participants (only one eye with functional vision) or participants fit with only one lens
5. Any moderate or severe ocular condition observed during the slit-lamp examination at the

enrolment visit
6. History of herpetic keratitis, ocular surgery or irregular cornea
7. Known pregnancy or lactation during the study period
8. 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
05/03/2020

Date of final enrolment
30/08/2020

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 (United States)

Sponsor details
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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 no specific plans for publication or dissemination of the study results. However, an abstract for submission at an ophthalmic conference may be generated.

Intention to publish date
30/08/2021

Individual participant data (IPD) sharing plan
The current data sharing plans for this study are unknown and will be 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		28/01/2021	28/01/2021	No	No