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Optimizing vision with multifocal contact lens combinations fitting in the clinic

Submission date
21/01/2019

Recruitment status
No longer recruiting

Registration date
23/01/2019

Overall study status
Completed

Last Edited
15/04/2020

Condition category
Eye Diseases

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

Plain English summary of protocol

Background and study aims
Multifocal contact lenses allow the wearers to see at all distances. For the best visual performance with multifocal contact lenses, typically one eye (the dominant one) will be fully corrected for distance vision and the other eye (non-dominant) will be biased towards intermediate and near vision. The aim of this study is to select the optimum lens power combinations for each eye to achieve the best distance and intermediate/near vision outcome with both eyes.

Who can participate?
Adults who are at least 40 years old and who have healthy eyes other than needing a near vision correction

What does the study involve?
Each participant has their eyes examined by the investigator and then fitted with two types of multifocal contact lenses according to their spectacle corrections and with additional plus or minus corrections in each eye. By reading letters of different sizes from various distances (far, intermediate and near), a series of vision measurements are taken with each of the pairs of multifocal contact lenses combination and corrections, and participant satisfaction is recorded on a 0-100 scale. All participants undergo the same series of vision tests and tasks.

What are the possible benefits and risks of participating?
Participants may not directly benefit from participation in this study. They may, however, contribute to research that may be used in the development of new, perhaps more successful, contact lenses. The examination and assessments are free and can be considered beneficial. All contact lenses have the potential of causing serious injury to the eye. Due to the nature and duration of the study the risks of participating in this study are considered to be similar to those of normal contact lens wear.

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?
March 2017 to December 2017

Who is funding the study?
CooperVision, Inc. (USA)

Who is the main contact?
Ms Trisha Patel

Contact information

Type(s)
Public

Contact name
Ms Trisha Patel

Contact details
66 Buckingham Gate
London
United Kingdom
SW1E 6AU

Additional identifiers

Protocol serial number
CV 17-20, OTGI 17-16

Study information

Scientific Title
Multifocal contact lens combinations fitting method optimization

Study objectives
The study is an exploratory study so no formal hypothesis is being formulated for the purpose of sample size calculation.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Yorkshire & The Humber - Bradford Leeds Research Ethics Committee Jarrow Business Centre Rolling Mill Road, Jarrow, NE32 3DT, Tel: +44 (0)207 104 8081, Email: nrescommittee.yorkandhumber-bradfordleeds@nhs.net, 04/04/2017, REC ref: 17/YH/0115, IRAS 225847

Study design
Single-center prospective randomized (testing order) double masked and non-dispensing study

Primary study design

Observational

Study type(s)
Screening

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

Interventions
Multifocal contact lens fitting for dominant and non dominant eye based on best sphere spectacle correction and over-refractions. Visual performance will be measured using letter charts and visual satisfaction with each contact lens combination will be recorded. This is a non-dispensing study involving 1 or 2 study visits (if a break is required). Participants will wear 2 multifocal contact lens types and power combination.

Intervention Type
Device

Primary outcome(s)
High contrast monocular and binocular visual acuities at distance (4 m), intermediate (67 cm) and near (40 cm) measured using letter charts in LogMAR during test visit

Key secondary outcome(s))
Visual satisfaction measured using visual analog scale (0-100) during test visit

Completion date
17/12/2017

Eligibility

Key inclusion criteria
There are no requirements as to participant race, gender or occupation.
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
3. Have read, signed and dated the Informed Consent
4. Current multifocal contact lens wearer
5. Spectacle refraction:
Distance:
Sphere: -6.00D to + 6.00D
Astigmatism: 0.00D to -0.75D
Near Addition:
Low Add: +0.75D to +1.25D
Mid Add: +1.50D & +1.75D
High Add: +2.00D to +2.50D
6. Best corrected visual acuity of at least 20/30 in each eye
7. Have normal eyes with the exception of the need for visual correction
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

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
To be eligible as a participant, each candidate shall be free of any ocular or medical condition that may affect the results of this study.
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 contact 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
8. Participation in any clinical trial within 30 days of the enrolment visit

Date of first enrolment
10/04/2017

Date of final enrolment
01/06/2017

Locations

Countries of recruitment
United Kingdom

England

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

Sponsor information

Organisation
CooperVision Inc. (USA)

Funder(s)

Funder type
Industry

Funder Name
CooperVision Inc. (USA)

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			15/04/2020	No	No
HRA research summary			28/06/2023	No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes