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Visual performance and satisfaction with multifocal contact lenses

Submission date	Recruitment status	[ ] Prospectively registered
02/08/2016	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
05/08/2016	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
06/09/2019	Eye Diseases	[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Presbyopia is a condition associated with aging in which the eye's ability to focus on near objects gradually becomes more difficult. Multifocal contact lenses can be used to help individuals with presbyopia to see objects both in the distance and up close; however, how well these contact lenses perform depends on the wearer's prescription, the activities that they are conducting and the lighting conditions. The purpose of this study is to measure vision with a series of multifocal contact lenses under various conditions of use.

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

What does the study involve?
Each participant have their eyes examined by the investigator and then are fitted with two to three types of multifocal contact lenses. A series of measurements of their vision are taken with each of the pairs of multifocal contact lenses. They are then asked to read letters of different sizes on both a computer screen and on smaller electronic tablets under bright, normal and dim lighting conditions. Each participant then completes a series of tasks while wearing the contact lenses. These include walking outdoor, carrying out a "word search" task and entering some data on a computer and reading and entering some details on a smart phone. The purpose of all of these tasks is not to see how well each participant completes them but for them to let the investigators know how satisfied they are with their vision while completing the tasks. All study participants will undergo the same series of vision tests and tasks.

What are the possible benefits and risks of participating?
The possibility exists that participants may not directly benefit from participation in this study. They may, however, contribute scientific research information 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. It is possible that the following problems may occur with the use of contact lenses: eyes stinging,

burning, itching (irritation) or other eye pain; comfort is less than when lens was first placed on the eye; feeling that something is in the eye such as a foreign body or scratched area; excessive watering (tearing) of the eye; unusual eye secretions; redness of the eye; reduced sharpness of vision (poor visual acuity); blurred vision, rainbows, or halos around objects; sensitivity to light (photophobia); or dry eyes. If a participant experiences any of these, they should let the investigator know as soon as possible. In rare instances, corneal ulcers, scarring, the growth of blood vessels into the cornea, temporary or permanent decreased vision, iritis and infections of the eye requiring treatment might occur.

Where is the study run from?
The study is being conducted by Ocular Technology Group – International and is being run at their research clinic at 66 Buckingham Gate, London SW1E 6AU (UK)

When is study starting and how long is it expected to run for?
July 2016 to December 2016

Who is the main contact?
Ms. Trisha Patel
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Contact information

Type(s)
Public

Contact name
Ms Trisha Patel

Contact details
66 Buckingham Gate
London
United Kingdom
SW1E 6AU

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
CV 16-51

Study information

Scientific Title
Visual performance and visual satisfaction measurement with multifocal contact lens combinations

Study objectives
No information is currently available regarding the relative visual performance and acceptance of the multifocal contact lens combinations to be tested. Therefore, the study will be an exploratory investigation to further the understanding of the effect of the optical design and fitting approach of multifocal contact lenses on visual performance and acceptance with a view to selecting the optimal lens designs for early, intermediate and advanced presbyopes.

No formal hypothesis is to be tested, however, the underlying assumptions for the study are that:
i. For specific visual environmental / activity situations the test combination achieving the best visual performance will also achieve the best visual acceptance;
ii. For specific visual environmental / activity situations the test combination achieving the best binocular summation (a marker of binocularity) will also achieve the best visual acceptance.

Ethics approval required
Old ethics approval format

Ethics approval(s)
National Research Ethics Committee - South Central - Berkshire B, 14/07/2016

Study design
Two phase, single arm, non-interventional, prospective, crossover study

Primary study design
Observational

Secondary study design
Case crossover study

Study setting(s)
Other

Study type(s)
Other

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet: +44 (0)20 7222 4224

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

Interventions
Visual performance will be measured binocularly (both eyes together) and monocularly (one eye at a time) using letter charts that are presented on either a monitor and on tablets (as applicable) at six distances under three lighting conditions (equivalent to outdoor daytime, indoor and outdoor nighttime). In addition participants will be asked to rate their satisfaction with their vision while wearing each of the contact lens types being evaluated.

The study will be conducted using a cross-over design. That is, each of the contact lenses to be evaluated will be worn as a pair, but the order that each of the pairs are worn in will be determined at random. All contact lens pairs will be worn by all participants in each of the study phases.

Intervention Type
Device

Phase
Not Specified

Primary outcome measure
This is a non-dispensing cross-over study and the primary endpoints will be measured at each of the visits when the test contact lenses are worn. There are a total of 2 to 3 test visits.
1. Measurement of binocular visual acuity at six distances (400, 200, 100, 67, 50, 40cm) at three luminance levels (250cd/m2, 50cd/m2 and 2.5cd/m2). Measurements will be made using letter charts with each of the types of contact lenses being evaluated
2. Visual satisfaction ratings on visual analogue scales and Likert scales with each of the types of contact lenses being evaluated

Secondary outcome measures
This is a non-dispensing cross-over study and the primary endpoints will be measured at each of the visits when the test contact lenses are worn. There are a total of 2 to 3 test visits.
1. Measurement of monocular (right and left eyes) visual acuity at six distances (400, 200, 100, 67, 50, 40cm) at three luminance levels (250cd/m2, 50cd/m2 and 2.5cd/m2). Measurements will be made using letter charts with each of the types of contact lenses being evaluated.

Overall study start date
14/06/2016

Completion date
31/12/2016

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 spectacle or soft contact lens wearer
5. Spectacle refraction:
Distance: Sphere: -6.00D to +4.00D; Astigmatism: 0.00D to -0.75D
Near Addition: Group 1 (Phase 1) - +1.00 to +1.50D; Group 2 (Phase 2) – Subgroup A +1.75 to +2.00D; Subgroup B +2.25 to +2.50D
6. Best corrected visual acuity in each eye of at least 20/25
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)
Other

Age group
Adult

Sex
Both

Target number of participants
A total of up 100 participants will be enrolled (50 in a low reading addition group and 50 in a medium or high reading addition group).

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
25/07/2016

Date of final enrolment
01/12/2016

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 Inc.

Sponsor details
5870 Stoneridge Drive, Suite 1
Pleasanton
United Kingdom
94588

Sponsor type
Industry

Funder(s)

Funder type
Industry

Funder Name
CooperVision Inc.

Results and Publications

Publication and dissemination plan
Since this study is an exploratory investigation designed to evaluate different optical designs and fitting approaches for multifocal contact lenses, there are no specific plans for publication or dissemination of the study results; however, an abstract for submission to an ophthalmic conference may be generated in which case the ISRCTN registration number would be provided.

Intention to publish date
31/12/2017

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available