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Satisfaction with multifocal contact lenses

Submission date
12/10/2016

Recruitment status
No longer recruiting

Registration date
28/10/2016

Overall study status
Completed

Last Edited
22/01/2018

Condition category
Eye Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] 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 people 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, their activities and lighting conditions. The aim of this study is to measure and compare the visual performance and visual satisfaction achieved with two pairs of multifocal contact lenses which are designed to correct distance, intermediate and near vision.

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

What does the study involve?
Participants' eyes are examined by the investigator and they are fitted with a pair of the first type of multifocal contact lenses. They are provided with a supply of these lenses to be worn on a daily disposable basis (wearing one pair each day and discarding it at the end of the day) and asked to return after a period of 7 to 10 days. At this time they are asked to complete a short questionnaire about the lenses and then the investigator measures their vision with the lenses. They are asked to read letters of different sizes on both a computer screen and on smaller electronic tablets under bright, normal and dim lighting conditions. They then remove the lenses and their eyes are once again examined by the investigator before they are fitted with a pair of the second type of multifocal lenses. They are provided with a supply of these lenses to be worn on a daily disposable basis to return after a further period of 7 to 10 days. At this time they are asked to complete a short questionnaire about the lenses and then the investigator measures their vision with these lenses. They then remove the lenses and their eyes are once again examined by the investigator. All study 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 taking part in this study, but the results of the study may contribute towards the development of new, perhaps more successful, contact lenses. The examination and assessments of the front part of the eye are at no cost to participants and can be considered beneficial by documenting their current health status. 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; 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. In rare instances, corneal ulcers (open sores on the eye), scarring, the growth of blood vessels into the cornea, temporary or permanently decreased vision, iritis (inflammation of the iris) and infections of the eye requiring treatment might occur.

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

When is the study starting and how long is it expected to run for?
October 2016 to January 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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
CV 16-63

Study information

Scientific Title
Visual satisfaction with a multifocal lens design combination: a randomized cross-over study

Study objectives
No information is currently available regarding the relative visual satisfaction and acceptance of the multifocal contact lens combinations to be tested when they are worn by individuals conducting everyday activities. 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. There is no formal hypothesis for this trial.

Ethics approval required
Old ethics approval format

Ethics approval(s)
National Research Ethics Committee - South West - Exeter, 22/09/2016, ref: 16/SW/0279

Study design
Single-arm prospective randomized cross-over study with investigator and participant masking

Primary study design
Interventional

Secondary study design
Randomised cross over trial

Study setting(s)
Other

Study type(s)
Treatment

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

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

Interventions
The two types of multifocal contact lenses to be tested differ in their power profiles across the lens (zones for distance, intermediate and near correction of vision). Participants' eyes will be examined by the investigator and they will be provided with a supply of the first type of lenses to be worn on a daily disposable basis (wearing one pair each day and discarding it at the end of the day) and asked to return after a period of 7 to 10 days. At this time they will be asked to complete a short questionnaire about the lenses and then the investigator will measure their vision with the lenses. They will be asked to read letters of different sizes on both a computer screen and on smaller electronic tablets under bright, normal and dim lighting conditions. They will then remove the lenses and their eyes will once again be examined by the investigator before they are fitted with a pair of the second type of multifocal lenses. They will be provided

with a supply of these lenses to be worn on a daily disposable basis to return after a further period of 7 to 10 days. At this time they will be asked to complete a short questionnaire about the lenses and then the investigator will measure their vision with these lenses. They will then remove the lenses and their eyes will once again be examined by the investigator before they are discharged from the study. All study participants will undergo the same series of vision tests and tasks.

Intervention Type
Other

Primary outcome measure
Subjective assessment of overall visual satisfaction, measured using a 100-point Visual Analog Scale (VAS) at the dispensing visit and follow-up visit for each of the lens types

Secondary outcome measures
Binocular visual performance, measured using high and low contrast LogMAR visual acuity charts at distance (4m), intermediate (67cm) and near (40cm) under high, medium and low levels of illumination, at the follow-up visit for each lens type

Overall study start date
03/10/2016

Completion date
22/02/2017

Eligibility

Key inclusion 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. 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 contact lens wearer
7. Spectacle refraction:
8. Distance: Sphere: -6.00D to + 4.00D, Astigmatism: 0.00D to -0.75D
9. Near Addition: +0.75D to +2.50D in three groups:
9.1. Emerging presbyopes: +0.75D to +1.25D
9.2. Established presbyopes:+1.50D and +1.75D
9.3. Advanced presbyopes: +2.00D to +2.50D
10. 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 40 participants will be enrolled

Key exclusion criteria
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 contraindicates as determined by the investigator
3. Monocular participants (only one eye with functional vision) or participants fit with only one 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

Date of first enrolment
03/10/2016

Date of final enrolment
31/12/2016

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Ocular Technology Group - International
United Kingdom
SW1E 6AU

Sponsor information

Organisation
CooperVision Inc.

Sponsor details
5870 Stoneridge Drive
Suite 1

Pleasanton
United States of America
94588

Sponsor type
Industry

Funder(s)

Funder type
Industry

Funder Name
CooperVision Inc.

Results and Publications

Publication and dissemination plan
To be confirmed at a later date

Intention to publish date
31/01/2018

Individual participant data (IPD) sharing plan
Participants are referred to by participant number and not name; however, initials and date of birth will be recorded on the study documents.
A web based data entry system is used to collect participant data. It is built around Entrypoint i4 (Phoenix Software International) which stores all data in a secure SQL database. Access is controlled by defining security profiles and associating each user with the appropriate profile. Every user must have a registered account with a unique name and password and a specified level of system authority. The software allows the generation of accurate and complete copies of records in both human readable and electronic form suitable for inspection, review, and analysis. Users with the right level of authority can view and print the data and reports of files. A dedicated server is used and the hardware is firewalled and is protected by antivirus software. The database is backed up daily and encrypted onto an external device. This encrypted data is then mirrored remotely to an external offsite location.
Participants are advised that their data are being collected for research purposes and may be used for additional scientific research, educational purposes and publications. Information will be encoded in order to safeguard their confidentiality, and if the results of the research are published or used in reports of the study or for scientific presentations, their identity will remain confidential. Any study information which is transferred to the Sponsor will be fully anonymised and neither the participant's identity or date of birth will be transferred; they will only be referred to by their participant number.
Participants are provided with all of the information relating to their confidentiality and how their data may be used in the Participant Information Sheet and provide written consent for this.

IPD sharing plan summary

Stored in repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No