ISRCTN63729760 https://doi.org/10.1186/ISRCTN63729760

Study of vision achieved with two contact lenses to correct presbyopia (the gradual loss of your eyes' ability to focus on nearby objects)

Submission date
28/01/2021

Recruitment status
No longer recruiting

Registration date
29/01/2021

Overall study status
Completed

Last Edited
03/02/2021

Condition category
Eye Diseases

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

Plain English summary of protocol

Background and study aims
Presbyopia is the gradual loss of your eyes' ability to focus on nearby objects. It's a natural, often annoying part of ageing. Presbyopia usually becomes noticeable in your early to mid-40s and continues to worsen until around age 65.
Multifocal contact lenses (contact lenses that correct both distance and near vision for people who need reading glasses) come in very different designs some giving better vision at near or at distance. In order to improve this type of contact lenses it is important to compare how well different designs are tolerated by patient and correct vision.
The study compares the level of vision satisfaction and the visual acuity achieved by two different contact lenses designs currently available.

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 pair is used first is randomly determined like tossing a coin). The second visit takes place one 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 pair, which they wear for one 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?
October 2018 to June 2019

Who is funding the study?
CooperVision Inc (USA)

Who is the main contact?
Deborah Moore
dmoore@otg.co.uk

Contact information

Type(s)
Public

Contact name
Ms Deborah Moore

Contact details
66 Buckingham Gate
London
United Kingdom
SW1E 6AU
+44 (0)2072224224
dmoore@otg.co.uk

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
263503

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
IRAS 263503, ID19-08 CV19-29

Study information

Scientific Title
Clariti® multifocal contact lens performance study

Study objectives

The overall visual acceptance with the two near addition system will not be inferior to the three near addition system.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 23/04/2019, London - Stanmore Research Ethics Committee (Skipton House, 80 London Road, London, SE1 6LH, UK; +44 (0)207 972 2561; stanmore.rec@hra.nhs.uk), ref: 19/LO/0574

Study design
Single-centre prospective randomised (testing order) double-masked cross over study

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 contact details to request a participant information sheet

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

Interventions
The study is a cross over study, the participants wear two CE-marked multifocal contact lenses each for a period of 7 +2/-0 days:
1. clariti® 1-day multifocal (test)
2. MyDay® multifocal combined with clariti® 1-day multifocal (control)
The order of testing will be randomised using a standard computerised randomisation software.

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Contact lenses, MyDay® multifocal, clariti® 1-day multifocal

Primary outcome measure

Overall binocular vision satisfaction measured on a 100-point visual analogue scale (VAS) after 1 week of wear

Secondary outcome measures
Overall binocular visual performance measured by LogMAR visual acuity after 1 week of wear

Overall study start date
01/10/2018

Completion date
14/06/2019

Eligibility

Key inclusion criteria
1. Aged at least 40 years
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:
Distance: Sphere: -6.00D to + 4.00D
Astigmatism: 0.00D to -0.75D
Near Addition: +0.75 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
60

Total final enrolment
20

Key exclusion criteria
1. Ocular anterior segment infection, inflammation, abnormality, or active disease that would contraindicate contact lens wear
2. Newly prescribed use of some 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 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
25/04/2019

Date of final enrolment
07/06/2019

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
6150 Stoneridge Mall Rd
Suite 370
Pleasanton
United States of America
CA 94588
+1 9252516682
plazon@coopervision.com

Sponsor type
Industry

Website

https://coopervision.co.uk/

Funder(s)

Funder type
Industry

Funder Name
CooperVision Inc. (USA)

Results and Publications

Publication and dissemination plan
The protocol and statistical analysis plan are confidential documents from the sponsor and have been reviewed by the Ethics Committee under usual confidentiality conditions. There are no specific plans for publication or dissemination of the study results. However, an abstract for submission at an ophthalmic conference and/or a peer-reviewed publication may be generated.

Intention to publish date
01/07/2021

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		03/02/2021	03/02/2021	No	No
HRA research summary			28/06/2023	No	No