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A research study to evaluate a novel type of near vision correction with contact lenses

Submission date
29/06/2016

Recruitment status
No longer recruiting

Registration date
19/07/2016

Overall study status
Completed

Last Edited
15/07/2016

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 chronic, age-related gradual loss of the ability of the eye to change focus in order to be able to see objects at near distances. Current optical options for patients with presbyopia include reading glasses, bifocal and multifocal glasses and contact lenses, and in some cases refractive surgery is performed. Contact lens vision correction is achieved using monovision contact lenses (where one eye is fully corrected for the distance and the other eye is corrected for the near vision) or multifocal contact lenses (both eyes have distance and near vision correction). The aim of this study is to evaluate a new type of near vision correction with commercially available contact lenses.

Who can participate?
Patients at least 50 years of age who have presbyopia

What does the study involve?
Each participant wears two different types of contact lenses for about 1 to 1.5 hours each in a randomly allocated order. Visual performance is measured by detecting changes in eye position related to near vision tasks.

What are the possible benefits and risks of participating?
There is no direct medical benefit to you, but the information obtained in this study may be helpful to others who wear contact lenses in the future. The risks of the study lens are similar to those of wearing any type of soft contact lens. These include eye irritation, pain, redness and swelling; a painful scrape or scratch on the surface of the clear part of the eye; blurred vision and sensation of dry eyes. Participants may get an infection from the contact lens or have an allergy to lens components. Comfort of the lenses may not be fully optimized for participants and they may experience discomfort. These risks may be mild to severe and may go away on their own or require treatment. Additionally, there may be side effects that are not known at this time. Participants are advised that if they develop any adverse symptoms (pain, swelling, redness, blurred vision, sensation or dry eyes) within 24 hours after wearing the study lenses, they should contact the Investigator immediately.

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?
December 2015 to June 2016

Who is funding the study?
Verily Life Sciences, LLC (USA)

Who is the main contact?
Trisha Patel

Contact information

Type(s)
Public

Contact name
Ms Trisha Patel

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Additional identifiers

Protocol serial number
2015-AL-001

Study information

Scientific Title
Investigation of visual acuity with near-intermediate monovision contact lens correction

Study objectives
To demonstrate superiority of high contrast near visual acuity (HC-NVA) and low contrast intermediate visual acuity (LC-IVA) with a near-intermediate commercially-available monovision contact lens correction as compared to a commercially-available multifocal contact lens correction.

Ethics approval required
Old ethics approval format

Ethics approval(s)
London - Queen Square Research Ethics Committee, 02/02/2016, REC ref: 16/LO/0234

Study design

Prospective crossover single-center feasibility study

Primary study design
Interventional

Study type(s)
Treatment

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

Interventions
Prospective crossover single-center feasibility study of two presbyopia-correcting contact lens systems. Up to 130 subjects will be randomized. Each subject will wear one Test Lens System (AIROPTIX AQUA) and one Control Lens System (AIROPTIX AQUA - Multifocal) in a randomized fashion for approximately 1 to 1.5 hours each. A randomization table will be generated assigning each subject into a specific order of lens wear. Subjects will be randomly assigned in a 1:1 fashion.

Intervention Type
Device

Primary outcome(s)
1. High-contrast near visual acuity (HC-NVA)
2. Low-contrast intermediate visual acuity (LC-IVA)

Measured at both the visit when the test contact lens system is being worn and the visit when the control contact lens system is being worn.

Key secondary outcome(s))
1. Low-contrast near visual acuity (LC-NVA) and stereopsis
2. The safety endpoints are biomicroscopy findings and adverse events

Measured at both the visit when the test contact lens system is being worn and the visit when the control contact lens system is being worn.

Completion date
30/06/2016

Eligibility

Key inclusion criteria
1. Healthy and competent, as determined by the Investigator
2. At least 50 years of age
3. Able to read and speak English
4. Able and willing to sign written Informed Consent Form
5. Must be a current or former contact lens wearer
6. Must have at least 20/25 distance and near vision in each eye best corrected
7. Must use a presbyopic reading correction of at least +2.25 diopters
8. Must have < or = 1.00D astigmatism

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
1. Eye injury within 12 weeks immediately prior to enrollment for this study
2. Anterior segment infection, inflammation, abnormality or any other anterior segment ocular disease that contraindicates contact lens wear as determined by the Investigator
3. Any use of systemic or ocular medications for which contact lens wear could be contraindicated as determined by the Investigator
4. History of herpetic keratitis
5. History of refractive surgery or irregular cornea
6. History of multifocal or monovision intraocular lens replacement surgery
7. > 1.0mm anisocoria
8. Slit lamp findings (at baseline) that are more severe than mild findings (greater than grade 2)
9. Corneal vascularization greater than 1 mm of penetration
10. A clinically significant dry eye determined by the Investigator
11. Participation of the subject in a clinical contact lens study (including contact lens or contact lens care product) within the previous 30 days
12. The Investigator, family members of the Investigator, family members of the Investigator's staff, or individuals living in the households of the aforementioned persons
13. Any additional condition or situation that, in the opinion of the Investigator, makes the subject inappropriate for participation in the study

Date of first enrolment
22/02/2016

Date of final enrolment
30/06/2016

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Ocular Technology Group - International
66 Buckingham Gate
London

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Sponsor information

Organisation
Verily Life Sciences LLC (USA)

ROR
https://ror.org/02e9yx751

Funder(s)

Funder type
Industry

Funder Name
Verily Life Sciences, LLC (USA)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes