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Comprehensive intermediate and near vision testing with trifocal intraocular lenses

Submission date
04/03/2020

Recruitment status
No longer recruiting

Registration date
10/03/2020

Overall study status
Completed

Last Edited
10/03/2020

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
As people get older, sometimes the lens of the eye becomes cloudy leading to loss of vision. The cloudy lens is known as a 'cataract'. The cataract can be removed and a replacement lens put in its place. The replacement lens known as ‘Trifocal’ lens has 'multiple focus'. People who get a trifocal intraocular lens (IOL) will be able to see well at all distances (far, intermediate and near) and do not require spectacles specifically for intermediate and near vision. The aim of this study is to evaluate the impact of different types of defocus on the intermediate and near visual performance of trifocal IOL and to measure intermediate and near vision with a comprehensive OTGi vision test system compared to a standard ETDRS vision test.

Who can participate?
People aged 18 years or older who had successful cataract surgery and both eyes implanted with trifocal IOL (at least 3 to 24 months)

What does the study involve?
The study comprises of one scheduled visit of approximately 4-5 hours. Participants will be given four different spectacle corrections in a random sequence and their intermediate and near vision will be measured with two different letter charts using high and low contrasts under standard room lighting. Participants will be asked to read out and identify the letters presented in the letter charts with both eyes. In total, 10 vision measurements (5 for intermediate vision and 5 for near vision) will be taken with each correction. Regular breaks will be provided. At the end of the visit the participant will be discharged from the study.

What are the possible benefits and risks of participating?
The potential benefit will be that the vision testing will be provided at no cost and may be beneficial in understanding how well the participants can see in different settings with their trifocal IOL. Due to the nature and duration of the study, the risks of participating are minimal. Participants will be reading letter charts from an intermediate (67 cm) and near (40 cm) position. All the assessments are safe, and none present any increased risk compared with a routine vision test.

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?
February 2019 to October 2019

Who is funding the study?
Ocular Technology Group – International with Alcon Research Investigator-Initiated Study Grant

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)

254198

Protocol serial number
OTGi ID 18-52, IRAS 254198

Study information

Scientific Title
Technology validation and optimization for Trifocal Intra Ocular Lens visual performance quantification

Study objectives
The different types of defocus and contrast conditions will have an impact on the intermediate and near visual performance of pseudophakic subjects implanted with trifocal IOLs. Comprehensive intermediate and near vision testing will provide better discrimination compared to standard testing.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 30/10/2018, Yorkshire & The Humber - Leeds East Ethics Committee (NHSBT Newcastle Blood Donor Centre, Holland Drive, Newcastle upon Tyne NE2 4NQ, UK; +44 (0)207 104 8081; nrescommittee.yorkandhumber-leedseast@nhs.net), ref: 18/YH/0430

Study design
Interventional randomized cross over trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Vision of pseudophakic patients implanted with trifocal IOLs

Interventions
Participants who have been implanted with trifocal IOLs will be wearing four different spectacle corrections at the clinic only (one study visit of approximately 4-5 hours). The investigator will examine the eyes, check the vision, spectacle prescription. After that, four different spectacle corrections will be worn in a random sequence and intermediate (67 cm) and near (40 cm) vision will be measured with two different letter charts (OTGi and ETDRS) using high and low contrasts and standard room lighting level. Participants will be asked to read out and identify the letters presented in the letter charts with both eyes. In total, 10 vision measurements (5 for intermediate and 5 for near) will be taken with each correction. Participants will be given regular breaks in between measurements. All study participants will undergo the same series of vision tests and tasks. At the end of the visit the participant will be discharged from the study.

The computer-generated randomization sequence will be applied to the order of the four spectacle corrections worn. For example: ID#1 order will be Spec 2, 4, 3, 1. ID#2 will be 1, 4, 2, 3 etc.

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Trifocal intraocular lens

Primary outcome(s)
Intermediate and near visual acuities in letters will be measured once using ETDRS charts (control) and OTGi vision suite (test) recorded in LogMAR with four corrections under the ten vision testing conditions with two different contrasts (high and low) and timed:
1. Best distance correction
2. Best distance correction & +0.50D spherical refractive blur
3. Best distance correction & -0.50D spherical refractive blur
4. Best distance correction & -1.00D cylinder axis 45

Key secondary outcome(s))
There are no secondary outcome measures

Completion date
31/10/2019

Eligibility

Key inclusion criteria
1. At least 18 years of age
2. Have read and understood the Participant Information Sheet and gave Informed Consent
3. Pseudophakic successfully implanted with AcrySof® PanOptix (TFNT00) or RayOne Trifocal by Rayner or Fine Vision Trifocal by PhysIOL IOLs bilaterally for at least 3 months but no longer than 24 months
4. Best-corrected visual acuity of at least +0.20 logMAR (20/32) in each eye
5. 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

Lower age limit
18 years

Sex
All

Key exclusion criteria
1. Ocular anterior segment infection, inflammation, abnormality, or active disease that would contraindicate study participation
2. History of any ocular surgical procedures or surgeries other than cataract surgery including but not limited to limbal relaxing incision (LRI), astigmatic keratotomy, laser-assisted in situ keratomileusis (LASIK), and retinal laser treatment
3. Use of systemic or ocular medications that could be contraindicated as determined by the investigator
4. Any moderate or severe ocular condition observed during the slit-lamp examination prior to study vision measurements
5. Known pregnancy or lactation during the study period

Date of first enrolment
01/02/2019

Date of final enrolment
30/10/2019

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Ocular Technology Group - International
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Sponsor information

Organisation
Ocular Technology Group International

Funder(s)

Funder type
Industry

Funder Name
Alcon Research Investigator Initiated Study Grant #IIT42375403

Alternative Name(s)

Funding Body Type
Government organisation

Funding Body Subtype
For-profit companies (industry)

Location
United States of America

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are not expected to be made available. This is an early feasibility study conducted by Ocular Technology Group in order to gain insights into vision testing protocol. Data will be held at the site.

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