In Vivo Straylight of Clareon/Vivinex IOLs

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON22813

Source
Nationaal Trial Register

Brief title
TBA

Health condition

Cataract

Sponsors and support

Primary sponsor: Coöperatie Medisch Specialistisch Bedrijf Amphia U.A.
Source(s) of monetary or material Support: Alcon Nederland B.V.

Intervention

Outcome measures

Primary outcome

The primary outcome parameter is the amount of straylight, expressed as the logarithm of the straylight value (log[s]), in eyes with implantation of a Clareon monofocal IOL or a Vivinex XY1 monofocal IOL.

Secondary outcome

Secondary study parameters are:

- The amount of straylight, expressed in log-units, over the course of 3 months after cataract surgery.
- (Relative) pixel intensities of the cornea, the (pseudo)phakic lens, the posterior lens capsule, and any vitreous opacities in measurements with the Pentacam and the IOLMaster 700,
- Uncorrected distance visual acuity (UDVA), (best-)corrected distance visual acuity (CDVA), determined with ETDRS visual acuity chart and expressed as the logarithm of the minimum angle of resolution (logMAR).
- Refractive error by means of automated refractometry, expressed as spherical equivalent (SEQ) refraction and as defocus equivalent (DEQ) refraction.
- Lens position, expressed as anterior chamber depth. Anterior chamber depth is defined as the distance from the central anterior corneal epithelium to the anterior part of the lens.
- Presence (and severity) of any opacities in the ocular structures in the slit lamp photographs.

Study description

Background summary

Rationale: Straylight is an optical phenomenon where light is scattered in the eye. It causes a veil of light over the retina and thereby reduces the contrast of the retinal image. In cataract, straylight strongly increases because of an increase in small particles in the crystalline lens. With cataract surgery, the opacified lens is removed and replaced by a clear artificial intraocular lens (IOL). This leads to a decrease in straylight after surgery and subsequent improvement of visual disturbances. However, IOLs scatter a varying amount of light as well; although, typically, less than the crystalline lens of a 20-year old. Nonetheless, straylight levels of the eye after cataract surgery do not fall below that of a 20-year old eye. It is not known what factors may increase straylight after cataract surgery. In addition, it is not known how the level of straylight changes in the immediate postoperative period and when it can be deemed stable. The Clareon and the Vivinex XY1 IOLs are two routinely used IOLs that are optically very clear. They thus are expected to have a very low amount of straylight. As of yet, however, no clinical studies have been performed studying straylight in eyes with implantation of these IOLs.
Objective: To study the amount of straylight in eyes of patients in the immediate postoperative period, investigate which parameters may affect straylight after cataract surgery, and study and compare the clarity characteristics of the Clareon and the Vivinex XY1 monofocal IOLs by assessing how it translates to straylight in actual patients.
Study design: prospective, comparative, single-arm, single center study.
Study population: 25 patients with cataract in both eyes, ≥18 years old.
Intervention: in each patient, one eye will receive a Clareon monofocal IOL and the fellow eye a Vivinex XY1 monofocal IOL.
Main study parameters/endpoints: The amount of straylight in eyes with implantation of a Clareon monofocal IOL or a Vivinex XY1 monofocal IOL.
Nature and extent of the burden and risks associated with participation, benefit and group

relatedness: Patients will have 7 site visits (not including the 2 visits for cataract surgery) on which they will receive a standard ophthalmological examination and measurements with various instruments. Their pupils will be dilated at each visit. Patients will receive 2 different monofocal IOLs in their eyes. Because these IOLs have been shown to be very comparable with respect to their clarity and color, we feel that risks are negligible for the patients.

Study objective

To explore the amount of straylight in patients implanted with a Clareon monofocal IOL in one eye and a Vivinex XY1 monofocal IOL in the other eye and compare these straylight values to those in the normal pseudophakic eye (i.e., the pseudophakic straylight norm).

Study design

Preoperative, 1 day post-op, 1 week post-op, 1 month post-op, and 3 months post-op.

Intervention

Patients will receive a Clareon monofocal IOL in one eye and a Vivinex XY1 monofocal IOL in the other.

Contacts

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Eligibility criteria

Inclusion criteria

• Diagnosis of cataract in both eyes,
• Having consented to and is planned to undergo cataract surgery in both eyes,
• Planned for implantation of a non-toric monofocal IOL,

• A targeted refractive error of emmetropia,
• Age of at least 18 years,
• Willing and able to participate in both preoperative and postoperative examinations, and
• Agreeing to sign the informed consent form.

Exclusion criteria

• Insufficient understanding of the Dutch language to comply with study procedures,
• Any comorbidity (other than cataract) that may significantly affect visual function and/or increase straylight and/or prolong visual recovery after surgery, such as significant macular degeneration, glaucoma, diabetic eye disease, ocular surface disease, corneal dystrophy, corneal opacification, significant vitreous opacities (such as asteroid hyalosis and clinically significant floaters), and history of cerebral vascular accident,
• Subjects with a history of ocular surgery (e.g., corneal refractive surgery),
• Subjects with an increased risk of complicated cataract surgery:
o Lens subluxation or (phaco)iridodonesis,
o Cataract brunescens, cataract rubra, cataract nigrans, or posterior polar cataract,
o History of ocular trauma
• Unability to be (reliably) measured with the C-Quant straylight meter, IOLMaster 700, and/or Pentacam,
• Unability to be (reliably) photographed with slit lamp photography,
• Corneal astigmatism of ≥3 diopters,
• A calculated IOL power for emmetropia in any eye that is outside the available range (i.e., Clareon IOL <6 D or >30 D and Vivinex XY1 IOL <6 D or >30 D).

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	N/A: single arm study
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	07-07-2020

Enrollment:	25
Type:	Anticipated

IPD sharing statement

Plan to share IPD: No

Ethics review

Positive opinion Date:	27-10-2019
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL8119
Other	MEC-U : R19.086

Study results