In Vivo Straylight of Clareon/Vivinex IOLs

Gepubliceerd: 27-10-2019 Laatst bijgewerkt: 18-08-2022

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...

Ethische beoordeling	Positief advies
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON22813

Bron
Nationaal Trial Register

Verkorte titel
TBA

Aandoening

Cataract

Ondersteuning

Primaire sponsor: Coöperatie Medisch Specialistisch Bedrijf Amphia U.A.
Overige ondersteuning: Alcon Nederland B.V.

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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).

Onderzoeksopzet

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

Onderzoeksproduct en/of interventie

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

Contactpersonen

Publiek

Amphia Ziekenhuis
Nic Reus

0031765952293

Wetenschappelijk

Amphia Ziekenhuis
Nic Reus

0031765952293

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

• 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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

• 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).

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	07-07-2020
Aantal proefpersonen:	25
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nee

Ethische beoordeling

Positief advies

Datum:	27-10-2019
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten