Global Multicenter Study with the Hydrophobic Acrylic (HF) Iris-Fixated PIOL for the Correction of Myopia in Phakic Eyes

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The HF IF PIOL can safely and effectively correct myopia in patients with low to high myopia and who have otherwise healthy eyes.

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

Samenvatting

ID

NL-OMON28006

Bron
Nationaal Trial Register

Aandoening

Myopia, myopie, bijziendheid, short-sightedness

Ondersteuning

Primaire sponsor: OPHTEC BV
Overige ondersteuning: fund = initiator = sponsor

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

the adverse event rates, uncorrected and best-corrected visual acuity, 1 day to 6 months post-operative, not exceeding the reference safety and performance endpoint (SPE) rates as

defined the ISO grid (ISO 11979-7 Annex B), and cataract not exceeding 2%.

Toelichting onderzoek

Achtergrond van het onderzoek

The investigational device is the Hydrophobic Acrylic (HF) Iris-Fixated (IF) Phakic Intraocular Lens (PIOL). The product is indicated for the correction of stabilized axial myopia in patients aged 18 and older, when there are no compromising ocular or systemic pathology(ies). The device is intended for placement in the anterior chamber of the eye, fixated to the iris.

Doel van het onderzoek

The HF IF PIOL can safely and effectively correct myopia in patients with low to high myopia and who have otherwise healthy eyes.

Onderzoeksopzet

pre-operative, operative, day 1, week 1, month 1, month 3, month 6

Onderzoeksproduct en/of interventie

Bilateral implantation of PIOL to correct myopia. (control PIOL vs study PIOL)

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Age >18 years; Axial myopia that can be fully corrected with a PIOL within the power range of -2.0 to -14.5 D (i.e.: myopia ranging from approximately -1.5 to -15.5 D, depending on keratometry values); Anticipated subjective astigmatism not exceeding 1.5 D in both eyes; Stable refraction (¡À0.5 D; ¡À1.0 D for refractive errors>10.0 D), as expressed by manifest refraction spherical equivalent (MRSE) for ¡Ý12 months prior to surgery, verified by consecutive refractions and/or medical records or prescription history; CDVA ¡Ý0.5 in each eye; UDVA ¡Ü 0.5 in each eye; Difference between cycloplegic and manifest refractions < 0.75 D; Current contact lens wearer has a stable refraction (¡À 0.5 D) on 2 consecutive examination dates at least 7 days apart, and the lenses were not worn for at least 2 weeks for rigid and toric contact lenses, or 3 days for spherical soft contact lenses prior to the first refraction;Minimum ACD of 3.2 mm (from epithelium to anterior lens capsule) by biometry, resulting in a critical distance between PIOL and endothelium of 1.5 mm or more as simulated with anterior segment imaging; Age specific, minimum endothelial cell density as follows (according to ISO11979-10):
18 to 25 years of age 2800 cells/mm2;
26 to 30 years of age 2650 cells/mm2;
31 to 35 years of age 2400 cells/mm2;
36 to 45 years of age 2200 cells/mm2;
> 45 years of age 2000 cells/mm2
Any subject who is expected to have residual postoperative cylindrical refractive error of up to 1.5 D has been given the opportunity to experience his/her best spectacle vision with anticipated spherical correction only, and is willing to proceed with the surgery; Availability, willingness and sufficient cognitive awareness and physical ability to comply with examination procedures throughout the entire duration of the study. No secondary surgical procedure planned during the course of the study (e.g. laser treatment to correct astigmatism).

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

Ocular condition that can predispose for future complications or interfere with the ability to evaluate the safety or effectiveness of the lens; Acute or chronic disease or illness that would increase the operative risk or confound the outcome(s) of the study; Use of systemic or ocular medications that can confound the outcome of the study or increase the risk to the subject; Concurrent participation or participation during the last 30 days in any other clinical trial; Prior intraocular or corneal surgery; Patient, when examined preoperatively, not expected to achieve a postoperative CDVA of 0.5 or better; Insufficient space for the intended

implant (ACD measured from epithelium <3.2 mm); Abnormal iris (e.g. bulging or volcano shaped iris, aniridia); Lens rise ¡Ý600 ¦Ìm; Abnormal cornea (e.g., keratoconus, opaque cornea, recurrent erosion syndrome, scars, or other cornea pathologies); Abnormal pupil (e.g. nonreactive, fixed, photopic diameter <2.0 mm); Ectopic pupil (>2 mm displacement from geometric center of cornea); Pupil >7 mm under scotopic conditions; Ocular hypertension (>21 mm Hg) Less than the minimal endothelial cell density as listed under inclusion criteria; Coefficient of variation of endothelial cell area ¡Ý0.45 (in both eyes); Endothelial disease that may potentially affect the visual outcome; History of retinal detachment; Evidence of retinal vascular disease or history of hypercoagulability; Glaucomatous changes in the retina or visual field; Glaucoma or glaucoma suspect; Any form of cataract; Corticosteroid responder; Active intraocular inflammation or recurrent ocular inflammatory condition; Monocular vision; Amblyopia;Microphthalmos or macrophthalmos; Immuno-compromised by steroids and/or antimetabolites; Pregnant, lactating, or plans to become pregnant during the course of the study Condition associated with fluctuation of hormones that could lead to refractive changes; Diabetes mellitus; Mentally retarded; Aged under 18; Surgical difficulty at the time of surgery which might increase the potential for complications; Not able to meet the extensive postoperative evaluation requirements.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-07-2014
Aantal proefpersonen:	125
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	28-01-2014
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	NL4281
NTR-old	NTR4425
Ander register	: METC-13-1-126.3/ab

Resultaten