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

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The purpose of the study is to investigate the safety and effectiveness of the HF IF PIOL, and to compare performance with the Artiflex lens. Study outcomes will be used to obtain CE marking for the lens and for registration and marketing purposes.

Ethical review	Approved WMO
Status	Pending
Health condition type	Vision disorders
Study type	Interventional

Summary

ID

NL-OMON40527

Source
ToetsingOnline

Brief title
HF IF PIOL Multicenter Study

Condition

- Vision disorders

Synonym
myopia, nearsightedness

Research involving
Human

Sponsors and support

Primary sponsor: OPHTEC BV

Source(s) of monetary or material Support: OPHTEC BV

Intervention

Keyword: hydrophobic acrylate, intraocular lens, iris-fixated, ophtec

Outcome measures

Primary outcome

To evaluate the safety and effectiveness of the HF IF PIOL, by documenting:

• adverse event rates and best-corrected visual acuity (BCVA), 6 months post-operative (safety);

• the improvement in uncorrected distance visual acuity (UDVA) at 6 months post operative (efficacy);

• the predictability (attempted versus achieved) of the MSRE;

• the stability of spherical equivalent;

• the endothelial cell density decrease after stabilization of the surgically induced cell loss (1to 6 months post-operative);

• subject satisfaction on resulting visual outcome.

In these, establishing the safety profile using adverse event rates and visual acuity is considered the primary objective of the study. Additional objectives are considered secondary.

Secondary outcome

The secondary objective is to compare the safety and effectiveness of the study lens with the Artiflex Myopia PIOL. The outcome of the comparison will be used to determine how the study lens performs compared to the Artiflex Myopia PIOL,

especially regarding occurrence of deposits and endothelial clearance, with a

comparable safety profile.

Study description

Background summary

Phakic intraocular lens (PIOL) implantation is a technique to correct refractive errors. Since the development of the Artisan Aphakia and its first use in cataract surgery in 1978, OPHTEC BV has introduced a range of iris-fixated products, each recognizable by the unique *iris claw* fixation principle on which the design is based. This fixation principle is extremely versatile, and allows positioning of the lens in any meridian and centered on the pupil. Once fixated, the lens does not rotate and remains at the same position.

In 1986 the Artisan Phakic IOL for myopia with a biconcave optic was the first PIOL to be introduced on the market by OPHTEC BV. Following the Feasibility Study with the biconcave optic, the configuration of the original biconcave lens was changed into a convex-concave design in 1991 to reduce potential complications. The Multicenter Study that was set up as a result of the design change demonstrated that the lens is safe, efficient, predictable and stable. Introduction of the Artisan for hyperopia and Artisan PIOL for myopia with an optic diameter of 6.0 mm followed in 1992 and 1997 respectively. The Artisan Myopia lens was FDA approved in 2004. In 1999, the Multicenter Study with the Toric Artisan PIOL for the correction of myopia and hyperopia in combination with astigmatism was started. The results demonstrated that implantation of the Toric Artisan PIOL is a safe, predictable and effective way to reduce ametropia and astigmatism in a single procedure. The Toric Artisan was introduced to the market in 2001.

Modern cataract surgery with phacoemulsification through a small *sutureless* wound stimulated OPHTEC BV to develop a foldable PIOL. After demonstrating the safety, efficacy, predictability and stability of the lens in a Multicenter Study that started in 2003, the introduction of the foldable Iris-Fixated Myopia Artiflex PIOL followed in 2005. Continuing on this path of development, OPHTEC BV introduced a toric version of the PIOL, the Artiflex Toric in 2009. In this lens, the possibility to correct astigmatism in one procedure and the advantages of a foldable lens are combined. Despite the clinical success of the Artiflex lenses, an aspect of improvement remains the occurrence of pigment and non-pigment precipitates that form on the lens optic in a low percentage of patients and which requires treatment with corticosteroids.

In its constant search for innovative products, OPHTEC BV now developed the hydrophobic acrylic (HF) iris-fixated (IF) PIOL for the correction of myopia. This lens combines advantages of the Artisan and Artiflex lenses.

Study objective

The purpose of the study is to investigate the safety and effectiveness of the HF IF PIOL, and to compare performance with the Artiflex lens. Study outcomes will be used to obtain CE marking for the lens and for registration and marketing purposes.

Study design

The study is a prospective, single-blind, randomized, multicenter, comparative clinical evaluation in low to highly myopic eyes. Estimated enrollment time is 3 months with a follow-up period of 6 months. For the main objective of establishing safety and effectiveness of the HF IF PIOL, an uncontrolled study design approach will be used. Following ISO 11979-7:2006 annex A, the number of subjects to be enrolled in such a design is 125, to achieve a minimum of 100 evaluable patients. As all subjects also receive the Artiflex Myopia PIOL in the non-study eye, safety and effectiveness of the HF IF PIOL will also be compared with the Artiflex Myopia PIOL as a secondary objective.

Intervention

Subjects will receive the HF IF PIOL in one randomly assigned eye and the CE certified Artiflex Myopia PIOL in the other eye. Surgical procedure and medication regime are standard for phakic iris-fixated lens implantation.

Study burden and risks

Benefits of PIOL implantation are spectacle and contact lens independence, a high level of comfort and high image quality. The clinical study may prove the clinical safety and effectiveness of the HF IF PIOL and superiority over the Artiflex PIOL. If the study results in CE marking of the lens, future patients may benefit from the improved product (compared to existing iris-fixated PIOLs). For study subjects, the primary benefit from implantation of the HF IF PIOL may be improved distance vision and spectacle independence. Secondary benefits compared to implantation of the Artiflex and Artisan PIOLs will be assessed in the clinical trial as secondary objectives.

Risks are deemed identical to Artiflex implantation and are listed in the instructions for use as complications. Risks were reduced to broadly acceptable risk (BAR) or as low as reasonably possible (ALARP) level. Product safety and performance are in accordance with specifications. Product design is in accordance with its intended use. Residual risks to be evaluated in the

clinical trial are occurrence and severity of deposits on the PIOL (i.e. iris pigment and non-pigment precipitates), and occurrence and severity of glare and halos.

Most complications can be avoided by careful patient selection according to the IFU. The severity of complications can be limited by early detection and treatment. Compliance with the postoperative monitoring recommendations is therefore crucial. If patient selection and postoperative monitoring are performed as per protocol, benefits to the patient outweigh the risks of participation to the clinical trial.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

• 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 (±0.5 D; ±1.0 D for refractive errors>10.0 D), as expressed by manifest refraction spherical equivalent (MRSE) for >=12 months prior to surgery, verified by consecutive refractions and/or medical records or prescription history;
• CDVA >=0.5 in each eye;
• UDVA <= 0.5 in each eye;
• Difference between cycloplegic and manifest refractions < 0.75 D;
• Current contact lens wearer has a stable refraction (± 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).

Exclusion criteria

• 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 <3.2mm);
• Abnormal iris (e.g. bulging or volcano shaped iris, aniridia);
• 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 >=0.45 (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.

Study design

Design

Study phase:	3
Study type:	Interventional
Intervention model:	Other
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)

Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-06-2015
Enrollment:	100
Type:	Anticipated

Medical products/devices used

Generic name:	Phakic intraocular lens
Registration:	No

Ethics review

Approved WMO Date:	19-11-2014
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

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
Other	Nederlands Trial Register: NTR4425
CCMO	NL46242.068.13