Prospective multicentre clinical trial with the Artiflex Presbyopic, an iris-fixated multifocal intraocular lens for the correction of presbyopia in phakic eyes

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The main objective of this study is to evaluate the safety and effectiveness of the Artiflex Presbyopic IOL. It will be studied whether the IOL can provide satisfactory near, intermediate, and distance vision in subjects who desire spectacle...

Ethical review	Approved WMO
Status	Will not start
Health condition type	Vision disorders
Study type	Interventional

Summary

ID

NL-OMON54294

Source
ToetsingOnline

Brief title
Clinical Trial With Artiflex Presbyopic

Condition

- Vision disorders

Synonym
ametropia, presbyopia

Research involving
Human

Sponsors and support

Primary sponsor: OPHTEC BV

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

Intervention

Keyword: Artiflex, iris-fixated multifocal IOL, Ophtec, phakic IOL

Outcome measures

Primary outcome

Improvement in monocular and binocular uncorrected near visual acuity (UNVA)

• Percentage of eyes that achieve UNVA of 0.3 logMAR or better

• Percentage of eyes that achieve UNVA of 0.0 logMAR or better

Improvement in monocular and binocular corrected near visual acuity (CNVA)

• Percentage of eyes that achieve CNVA of 0.3 logMAR or better

• Percentage of eyes that achieve CNVA of 0.0 logMAR or better

Improvement in monocular and binocular distance corrected near visual acuity (DCNVA)

• Percentage of eyes that achieve DCNVA of 0.3 logMAR or better

• Percentage of eyes that achieve DCNVA of 0.0 logMAR or better

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Improvement in monocular and binocular uncorrected intermediate visual acuity (UIVA)

• Percentage of eyes that achieve UIVA of 0.3 logMAR or better

• Percentage of eyes that achieve UIVA of 0.0 logMAR or better

Improvement in monocular and binocular distance corrected intermediate visual

acuity (DCIVA)

• Percentage of eyes that achieve DCIVA of 0.3 logMAR or better

• Percentage of eyes that achieve DCIVA of 0.0 logMAR or better

Improvement in monocular and binocular uncorrected distance visual acuity (UDVA)

• Percentage of eyes that achieve UDVA of 0.3 logMAR or better

• Percentage of eyes that achieve UDVA of 0.0 logMAR or better

Improvement in monocular and binocular corrected distance visual acuity (CDVA)

• Percentage of eyes that achieve CDVA of 0.3 logMAR or better

• Percentage of eyes that achieve CDVA of 0.0 logMAR or better

Defocus evaluation

• Binocular defocus evaluation will be obtained by using the best corrected distance refraction and then defocusing the image in 0.5 D increments from +1.5 to -5.0 D.

Predictability of the manifest refraction spherical equivalent (MRSE)

• The absolute difference between the actually obtained MRSE and the target MRSE

• The percentage of eyes that achieves a MRSE of less than or equal to 0.5 D difference between the actual and target MRSE

• The percentage of eyes that achieves a MRSE of less than or equal to 1.0 D difference between the actual and target MRSE

Stability of manifest refraction spherical equivalent (MRSE)

• Mean change in MRSE between visits as determined by a paired analysis

• The percentage of eyes that achieves a change in MRSE of less than or equal to 0.5 D between two consecutive refraction measurements

• The percentage of eyes that achieves a change in MRSE of less than or equal to 1.0 D between two consecutive refraction measurements

Spectacle dependency

• Percentage of subjects that uses glasses for near vision and the frequency of use

• Percentage of subjects that uses glasses for intermediate vision and the frequency of use

• Percentage of subjects that uses glasses for distance vision and the frequency of use

• Percentage of subjects that achieve complete spectacle independence

Contrast sensitivity

• Postoperative binocular photopic contrast sensitivity scores for spatial frequencies of 3, 6, 12 and 18 cycles per degree (cpd)

• Postoperative binocular mesopic contrast sensitivity scores for spatial frequencies of 3, 6, 12 and 18 cpd

• Postoperative binocular photopic contrast sensitivity scores in the presence of glare for spatial frequencies of 3, 6, 12 and 18 cpd

• Postoperative binocular mesopic contrast sensitivity scores in the presence

of glare for spatial frequencies of 3, 6, 12 and 18 cpd

• Comparison of the preoperative and postoperative photopic and mesopic contrast sensitivity scores with and without the presence of glare

Quality of Vision

• Percentage of subjects that experiences different visual disturbances is evaluated by a validated questionnaire

• The occurrence of the different visual disturbances

• The severity of the different visual disturbances

• The bothersomeness of the different visual disturbances

• The time of onset of visual disturbances

Satisfaction questionnaire

• Percentage of subjects that is satisfied with the overall procedure

• Percentage of subjects that is satisfied with uncorrected near vision

• Percentage of subjects that is satisfied with uncorrected intermediate vision

• Percentage of subjects that is satisfied with uncorrected distance vision

Endothelial cell density

• Comparison of the preoperative and postoperative endothelial cell density

• Endothelial cell loss over time

• Additionally, a comparison between the in the scientific literature reported naturally occurring endothelial cell loss over time (approx. 0.6% per year; Bourne et al., 1997) and the in the study observed cell loss will

be performed (EN-ISO 11979-10, section 10.2.1, page 3).

Adverse event (AEs) / complication rates

• Cumulative numbers of adverse events, e.g. cystoid macular edema (CME), hypopyon, endophthalmitis, lens dislocation, pupillary block, retinal detachment, necessary secondary surgical interventions.

• Cumulative numbers of adverse events persistently present, e.g. corneal stroma edema, cystoid macular edema, iritis, raised intraocular pressure (IOP) requiring treatment, lens deposits.

• The occurrence of adverse events will be compared to and should not exceed the reference safety and performance endpoint (SPE) rates as defined by ISO 11979-7:2018 (see CIP: Annex E, table E.1).

Secondary outcome

The following objectives are considered secondary:

- To evaluate contrast sensitivity

- To evaluate the defocus

- To evaluate rates of adverse events/complications

- To evaluate patient satisfaction and quality of vision

Study description

Background summary

Presbyopia is a very common, age-related impairment of near vision, with an average onset at approximately 45 years of age. Whereas in Europe and North-America about 83 percent of the population at the age of 45 years old and older are affected, the prevalence in Asia and South-America is considerably

lower with respectively 44 and 60 percent. Presbyopia is an impairment of near vision. Indeed, to be able to see at different distances (near, intermediate, and far) the eye has the ability to accommodate. During aging, the range of distances where the eye can focus properly reduces, which ultimately results in the loss of accommodation capability or presbyopia. Presbyopia may be - and is often - combined with other visual impairments such as myopia, hyperopia, and astigmatism. Historically, the treatment of presbyopia has primarily involved spectacles and contact lenses. However, since spectacles reduce the visual field and lenses are not tolerated by many subjects, alternative treatment methods - i.e. refractive laser surgery- are developed for the correction of refractive errors. Although laser refractive surgery can be a very effective procedure, it does not always lead to spectacle-independence. Furthermore, the rather invasive treatment has a limited power range when compared to intraocular lenses, and also carries several potential side effects and complications including, corneal scarring, dry eyes, and dysphotopsia. The newly by Ophtec developed phakic multifocal intraocular lens - the Artiflex Presbyopic - is based on two lenses currently manufactured by Ophtec, the Artiflex Myopia, a flexible phakic IOL intended for the correction of myopia, and the Precizon Presbyopic NVA IOL, which is indicated for the optical correction of aphakia and presbyopia in adult subjects and is intended for implantation in the capsular bag. The optical properties of the Artiflex Presbyopic are based on the multifocal Precizon Presbyopic NVA IOL. Presbyopic NVA IOL is known to provide satisfactory vision at al distances with a evel of minimum dysphotopsias like haloes and glare. Expectedly, Implantation of Artiflex Presbyopic is supposed to result in an improved near, intermediate and far visual acuity, and thereby in a complete spectacle independency.

Study objective

The main objective of this study is to evaluate the safety and effectiveness of the Artiflex Presbyopic IOL. It will be studied whether the IOL can provide satisfactory near, intermediate, and distance vision in subjects who desire spectacle independency. 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, open-label, single-arm, multicentre clinical investigation with the Artiflex Presbyopic IOL, intended to evaluate the performance - safety and efficacy - of the lens in adult phakic subjects with presbyopia. About 125 subjects will receive the Artiflex Presbyopic lens bilaterally and will be followed for a period of 3 years.

Intervention

Subjects receive the Artiflex Presbyopic multifocal IOL in both eyes. Surgical

procedure and medication regime are standard for intraocular lens implantation.

Study burden and risks

Implantation of the Artiflex Presbyopic IOL may result in an improved near, intermediate, and far visual acuity, and thereby in a complete spectacle independency. However, as mentioned previously, the implantation may be accompanied by lens-related complications like contrast sensitivity loss and the presence of dysphotopsia or photic phenomena. The loss of contrast sensitivity is related to the fact that a multifocal optic divides the incoming light over two or more focal points. Especially under mesopic conditions, this loss of contrast sensitivity can become clinically relevant. Photic phenomena may disturb vision or hinder the subject in normal functioning and are the leading cause for dissatisfaction after multifocal IOL implantation. In the worst case, the presence of certain complications might require a secondary surgical intervention, to for example exchange the lens for a different model. By careful selection, according to the exclusion criteria, most complications should be avoided. The regular postoperative examination should result in early detection, and thus treatment, of potential complications. If subject selection and postoperative monitoring are performed as per protocol, benefits to the subject outweigh the risks of participation in 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

•Presbyopic adult
•Potential for binocular vision
•Subject wishes to be spectacle independent for near and far vision
•Refractive error that can be corrected with correction at PIOL plane from +2.0 to -15.0 D
•Subject requiring a presbyopic correction
•Patients with reading glasses of minimum +1D.
•Stable refraction (±0.75 D), as expressed by manifest refraction spherical equivalent (MRSE) for a minimum of 12 months prior to surgery, verified by consecutive refractions and/or medical records or prescription history
•Expected best corrected visual acuity of 0.2 logMAR (0.63 Snellen decimal) or better after lens implantation
•Current contact lens wearer should demonstrate a stable refraction (± 0.5 D), expressed as subjective refraction spherical equivalent, on two consecutive examination dates performed at least 7 days apart. Before the first refraction, the contact lens wearer should not have worn lenses for at least 2 weeks in case of rigid and toric contact lenses, or 3 days for spherical soft contact lenses.
•Any subject, who is expected to have a residual postoperative cylindrical refractive error of below 0.75 D
•Ability to give informed consent
•Availability, willingness and sufficient cognitive awareness and physical ability to comply with examination procedures throughout the entire duration of the study

Exclusion criteria

•Preoperative ocular or systemic condition or medication use that would be expected to present undue risk to the subject, that can predispose for future complications or confound the outcome(s) of the study.
E.g. the systemic use of alpha-1a adrenergic receptor antagonists was suggested to increase the occurrence of intraoperative floppy iris syndrome, alter iris morphology - or more specifically reduce iris thickness at the site of potential IOL enclavation - and increase postoperative endothelial cell loss.
•Previous ocular surgery which might affect the outcome of the study

•Concurrent participation or participation during the last 30 days in another drug or device investigation
•Subjects with a distance corrected near visual acuity of better than 20/60 or 0.48 LogMAR.
•Secondary surgical procedure planned during the first 6 months of the study (e.g. laser treatment to correct astigmatism)
•Amblyopia
•Preoperative anterior chamber depth measurement of below 3.0 mm for subjects < 40 years old and 2.8 mm for subjects > 40 years old. Anterior chamber depth is measured from the corneal endothelium to the anterior pole of the crystalline lens. This will result in a critical distance between PIOL and endothelium of 1.5 mm or more as simulated with anterior segment imaging.
•White-to-white smaller than 10.5 mm
•Subjects not meeting the age specific minimum preoperative endothelial cell density as defined below:
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
•Corneas with high rates of polymegethism (a coefficient of variation over 0.40) and pleomorphism (the presence of less than 50% hexagonal cells).
•Abnormal iris (e.g. convex, bulging or volcano shaped iris)
•Crystalline lens rise of 600 µm or more
•Abnormal cornea (keratoconus, opaque cornea, corneal scars, post corneal transplant, corneal dystrophy, or other)
•Ocular surface conditions which might influence the quality of vision and affect the outcome of the study
•Abnormal pupil (e.g. nonreactive, fixed)
•Ectopic pupil
•Pupil in photopic light conditions smaller than 2.6 mm
•Pupil in scotopic light conditions greater than 7.0 mm
•High preoperative intraocular pressure (>21 mm Hg)
•Cataract of any grade
•Glaucoma or family history of glaucoma (dependent on the evaluation of physician)
• Diabetes or diabetic retinopathy
•Acute or chronic inflammation
•Chronic or recurrent uveitis or family history of the same condition
•Retinal detachments or family history of retinal detachments
•Corticosteroid responder
•Pregnant or nursing
•Aged under 18

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	15
Type:	Anticipated

Medical products/devices used

Generic name:	Intraocular Lens
Registration:	No

Ethics review

Approved WMO

Date:	23-12-2021
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

Approved WMO

Date:	18-01-2023
Application type:	Amendment
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
ClinicalTrials.gov	NCT04632784
CCMO	NL76222.000.21