Long-term follow up after implantation of Artisan Phakic Iris Claw Intraocular lens for the correction of high degree myopia

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To evaluate the long term safety, efficacy, predictability, stability, complications and patient satisfaction after implantation of Artisan phakic intraocular lenses for the correction of high degree myopia.

Ethical review	-
Status	Recruitment stopped
Health condition type	Eye disorders NEC
Study type	Observational non invasive

Summary

ID

NL-OMON39608

Source
ToetsingOnline

Brief title
Long term follow up of an Artisan IOL in high degree myopia / ARTIC-study

Condition

- Eye disorders NEC
- Therapeutic procedures and supportive care NEC

Synonym
myopia, shortsightedness

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W,SNOO

Intervention

Keyword: artisan, myopia, refractive surgery

Outcome measures

Primary outcome

To determine the safety, efficacy and predictability of visual outcome up to 15 years post-surgery, after an Artisan pIOL implantation for the correction of high degree myopia.

- Safety defined as >= 2 lines loss of the best spectacle corrected visual acuity in percentage compared to pre-surgery.
- Efficacy defined as the percentage of eyes with an uncorrected visual acuity >= 20/20.
- Predictability defined the manifest refractive spherical equivalent within +/- 1.0 diopters of the intended correction.

Secondary outcome

- Determine complications of an Artisan pIOL, in particular endothelial cell loss
- Determine the stability of an Artisan pIOL for the correction of high degree myopia by comparing short term data with long term data
- Observe long term complications associated with high degree myopia
- Determine the patients* satisfaction up to 15 years post-surgery after implantation of an Artisan pIOL

Study description

Background summary

Myopia, or shortsightedness, is a frequent eye disorder that may lead to blindness. There are currently no treatment options to stop progression or cure the complications. The causes of high myopia are still unknown. From epidemiologic studies, it has become clear that the disease is highly heritable. The current hypothesis is that myopia is a complex genetic disorder probably consisting of multiple genes with relatively small effect.
There are currently no treatment options available for stopping the progression of myopia. The optical correction of myopia can be achieved by spectacle lenses, contact lenses or by implantation of an intraocular lens.
Phakic intraocular lenses (pIOL) are implanted into the human eye in addition to the natural ocular lens. There are many different kinds of intraocular lenses. In 1998 the Artisan pIOL was introduced. The Artisan is a concave-convex phakic intraocular lens and is designed to be supported by the mid-iris tissue, also called an *iris claw*. Multiple short term follow up studies have shown that the Artisan pIOL is a safe and efficient method for correction of high myopia.
Only a limited amount of studies have been performed to evaluate the long term safety, efficacy, stability, predictability, complications and patient satisfaction of an Artisan iris claw phakic intraocular lens for correction of high degree myopia. Even fewer studies have evaluated the results after a post operative follow-up up to ten years. Evaluation of the long-term outcomes of implantation of an Artisan will help us determine the safety of this device. Insights into the long-term outcomes of implantation of an Artisan pIOL will help us determine the safety of this device and may help modification and development of future intraocular lenses for correction of high degree myopia.

Study objective

To evaluate the long term safety, efficacy, predictability, stability, complications and patient satisfaction after implantation of Artisan phakic intraocular lenses for the correction of high degree myopia.

Study design

The design is a retrospective observational study in which we will collect data on outcomes regarding the safety, efficacy, predictability, stability, complications and patient satisfaction in patients treated for high degree myopia with an Artisan iris fixated phakic intra ocular lens implant.

Study burden and risks

not applicable

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

- minimum 18 years of age and fully competent
- Sign an informed consent to participate in this study
- Artisan iris fixated phakic intra ocular lens implant for optical correction of high degree myopia (> S-6 diopters)
- Minimal postoperative follow up of 5 years
- Endothelial cell count performed pre-operative

Exclusion criteria

none

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	20-01-2011
Enrollment:	200
Type:	Actual

Ethics review

Approved WMO Date:	15-02-2012
Application type:	Amendment
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)
Approved WMO Date:	22-01-2014
Application type:	Amendment
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)

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
CCMO	NL32857.058.10