Comparing the effectiveness of the Vivinex iSert IOL to the Tecnis Eyhance IOL in standard cataract surgery

Published: 24-07-2019
Last updated: 10-04-2024

The aim of this research is to find out which lens gives the best results.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Eye disorders
Study type	Interventional

Summary

ID

NL-OMON48276

Source
ToetsingOnline

Brief title
Which IOL is better?

Condition

- Eye disorders
- Eye therapeutic procedures

Synonym
Cataract, clouding of the lens in the eye

Research involving
Human

Sponsors and support

Primary sponsor: Elisabeth-Tweesteden ziekenhuis
Source(s) of monetary or material Support: Johnson & Johnson Pharmaceutical,Johnson&Johnson

Intervention

Keyword: cataract surgery, Effectiveness, IOL's

Outcome measures

Primary outcome

The measurement of uncorrected and corrected intermediate visual acuity is the

primary endpoint of this study in which the Tecnis Eyhance IOL and the Hoya

Vivinex IOL are compared

Secondary outcome

NA

Study description

Background summary

With an estimated number of cataract extractions of 180.000 per year in the Netherlands, cataract surgery is one of the most frequently performed types of surgery.
Monofocal IOLs are the most implanted IOLs in cataract surgery and are the standard of care for reimbursed cataract procedures by health insurance companies. Using a reliable IOL plat-form with a monofocal lens that meets the highest standards of care is therefore the ultimate goal in selecting the right IOL. It*s therefor important to compare current monofocal IOL plat-forms that are being used nowadays for its effectiveness in standard cataract surgery. In this study we want to compare the Vivinex iSert© IOL (HOYA) to the newly introduced Tecnis Eyhance© IOL (Johnson & Johnson Vision).
Our hypothesis is that the new Eyehance iol performes better for intermediate visual acuity and has a flatter defocuscurve profile than the Vivinex iol which may result in more patients being independent of spectacle wear after standard cataractsurgery

Study objective

The aim of this research is to find out which lens gives the best results.

Study design

Single center, prospective, comparative, randomised clinical trial

Intervention

Cataract surgery using phacoemulsification in both eyes during two separate operations (operation session 1: eye 1, operation session 2: eye 2), where there is a minimum of two weeks between both operation sessions (is standard procedure). Randomization determines which lens is used, the Vivinex iSert IOL (control product) or the Tecnis Eyhance IOL (test product).

Study burden and risks

Potential benefits: the Eyehance lens has the potential to deliver more spectacle independan-ce for intermediate visual acuity than the Vivinex iol. Potential risks associated with participation are the possible complications of cataract surgery in general, most importantly the very rare but severe risk of endophthalmitis (ocular infection) and the risk of refractive surprise (a significant deviation from the predicted refraction). The risk on facing one of these complications is similar for both eyes, regardless of the time of surgery. Compared to usual care, the extra burden for all patients participating in this study is filling in questionnaires two times during the study, which will take about 15 minutes per time.

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

- Bilateral cataract
- Expected uncomplicated cataract surgery

Exclusion criteria

- Age < 18 years
- Insufficient understanding of the Dutch language to comply with study procedures and/or complete patient questionnaires
- Inability to complete follow-up or comply with study procedures
- Non-routine cataract surgery (e.g., cataract surgery combined with another ocular procedure, cataract surgery under general anesthesia)
- Cognitive or behavioral conditions that might interfere with surgery
- Cataract surgery with premium IOL implantation (i.e., toric IOLs, multifocal IOLs)
- Conditions that increase the risk of endophthalmitis:
* Current ocular, adnexal, or periocular infections (e.g., untreated blepharitis)
* Immune-compromised (e.g., systemic corticosteroid use, leukaemia)
* Iodine allergy
- Factors that increase the risk of refractive surprise:
* Abnormal axial lengths (< 21 mm or > 27 mm) or a difference between both eyes of > 1.5 mm
* Abnormal keratometry readings
* Previous refractive surgery
* Myopia with posterior staphylomas

- Conditions that increase the risk of corneal edema (e.g., Fuchs* endothelial dystrophy)
- Factors that increase the risk of complicated surgery:
* Previous ocular surgery
* Previous perforating or blunt eye trauma

* Eye, adnexal, or anatomical abnormalities (including pseudoexfoliation syndrome)
* Lens luxation or iridodonesis
* Cataract nigrans, posterior polar cataract
- Sight-threatening comorbidity
- Glaucoma or intraocular pressure of > 24 mmHg
- Uveitis
- Diabetes mellitus with diabetic retinopathy and macular edema.
- Any Macular disease

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	02-10-2019
Enrollment:	70
Type:	Actual

Ethics review

Approved WMO

Date:	24-07-2019
Application type:	First submission
Review commission:	METC Brabant (Tilburg)

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	NL70320.028.19