

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

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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 platform with a monofocal lens that meets the highest standards of care is therefore the ultimate goal in selecting the right IOL. It's therefore important to compare current monofocal IOL platforms 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 Eyhance iol performs better for intermediate visual acuity and has a flatter defocus curve profile than the Vivinex iol which may result in more patients being independent of spectacle wear after standard cataract surgery

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

Public

Elisabeth-Tweesteden ziekenhuis

Hilvarenbeekseweg 60
Tilburg 5022 GC
NL

Scientific

Elisabeth-Tweesteden ziekenhuis

Hilvarenbeekseweg 60
Tilburg 5022 GC
NL

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