Cataract Online Refraction Evaluation: A Multi Center Randomized Controlled Trial

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To determine non-inferiority of the corrected distance visual acuity (CDVA) with the prescription obtained through the web-based measurement of refractive error, compared to usual care, in patients who underwent routine cataract surgery.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Vision disorders
Study type	Observational non invasive

Summary

ID

NL-OMON52771

Source
ToetsingOnline

Brief title
CORE-RCT

Condition

- Vision disorders

Synonym
cataract. lens opacification

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht
Source(s) of monetary or material Support: easee BV,TKI Health Holland

Intervention

Keyword: cataract, digital health, digital refraction, e-health

Outcome measures

Primary outcome

costeffectiveness

Secondary outcome

Corrected distance visual acuity at the final post-operative visit, uncorrected distance visual acuity, refractive error (sphere/cylinder/axes), patient reported outcome measurements, adverse events.

Study description

Background summary

Cataract is widely prevalent in especially elderly and cataract extraction surgery has thus become one of the most performed surgeries worldwide. In recent decades the safety of cataract surgery has greatly improved and it is considered one of the safest surgeries to be performed. Postoperative management consists of routine examinations within one week, to ascertain no adverse events have occurred immediately after surgery, and between 4-6 weeks, to determine the refractive error. The incidence of serious adverse events following cataract surgery is estimated to be 1%. As a result, the majority of patient visits after cataract surgery will be uneventful. Nonetheless valuable time and hospital resources are consumed. Remote monitoring could replace clinical examinations in selected patient groups. However, this practice of digital remote monitoring which the patient can use independently has not been clinically validated yet.

Study objective

To determine non-inferiority of the corrected distance visual acuity (CDVA) with the prescription obtained through the web-based measurement of refractive error, compared to usual care, in patients who underwent routine cataract surgery.

Study design

Observational randomized trial without interventions

Intervention

Subjects in the telemonitoring group will have a post-operative follow-up by teleconsultations with online questionnaires and a web-based eye exam.

Study burden and risks

The "telemonitoring group" will perform web-based eye exams and fill out questionnaires at home at three time points after surgery. These take on average 20 minutes each. All participants (both groups) will fill out questionnaires on patient reported outcomes and quality of life, which take on average 15 minutes. All patients will receive a final clinical assessment 4-6 weeks after surgery to validate the telemonitoring outcomes, mitigating the risk of a residual refractive error after cataract surgery.

The risks are considered very low. The web-based eye exam has been tested and proven safe (CE-certified). The subjects of the "telemonitoring group" will have a telephonic consultation 1 day after surgery, this is in line with the Dutch Society of Opthalmolgy guideline of cataract surgery. When there are doubts, a physical consultation should be planed. After 4-6 weeks there will be a physical consultation in the hospital.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Elderly (65 years and older)

Inclusion criteria

- Planned for bilateral phacoemulsification cataract extraction and intra-ocular lens implantation (either sequential or in one procedure)
- >= 18 years of age
- No other current ophthalmic conditions or history that negatively influence post-operative visual acuity
- Be able to fill out the health questionnaires (in Dutch, German or English) and perform the web-based refractive assessment (possibly with assistance of family member or other close relative).
- Specific digital requirements include access to a computer and a smartphone and knowledge how to log in to an online patient portal.

Exclusion criteria

- Cataract extraction surgery combined with other procedures, including: keratoplasty, vitrectomy, glaucoma filter implants
- Ocular comorbidities that negatively influence post-operative visual acuity
- No access to the digital requirements to take the online health questionnaire and/or perform the online refraction.
- Insufficient command of the Dutch, German or English language to understand the questionnaires and instructions of the web-based refractive assessment or no family member / close relative to assist with this
- Inability of performing the web-based eye exam prior to cataract surgery.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	22-04-2021
Enrollment:	70
Type:	Actual

Medical products/devices used

Generic name:	Easee Online Eye Exam
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	01-03-2021
Application type:	First submission
Review commission:	METC NedMec
Approved WMO Date:	30-03-2021
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	09-07-2021
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	23-09-2021

Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	13-04-2022
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	27-05-2022
Application type:	Amendment
Review commission:	METC NedMec

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	NL74625.041.20