Cost-effectiveness of immediately versus delayed sequential bilateral cataract surgery (ISBCS vs. DSBCS)

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To evaluate the effectiveness and costs of immediately sequential bilateral cataract surgery (ISBCS) compared to delayed sequential bilateral cataract surgery (DSBCS; usual care) in order to determine whether ISBCS is an effective and cost-effective...

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

Summary

ID

NL-OMON50196

Source
ToetsingOnline

Brief title
Cost-effectiveness of ISBCS vs. DSBCS

Condition

- Eye disorders
- Eye therapeutic procedures

Synonym
Cataract, clouding of the lens in the eye

Research involving
Human

Sponsors and support

Primary sponsor: Medisch Universitair Ziekenhuis Maastricht
Source(s) of monetary or material Support: ZonMw

Intervention

Keyword: - Bilateral cataract surgery, - Cost-effectiveness, - Delayed sequential bilateral cataract surgery (DSBCS), - Immediately sequential bilateral cataract surgery (ISBCS)

Outcome measures

Primary outcome

Proportion of patients with a refractive outcome in the second eye that

deviates less than ± 1.0 dioptre from the target refraction (primary outcome).

Secondary outcome

- Proportion of patients with a refractive outcome in the second eye that

deviates less than ± 0.5 dioptre from the target refraction

- Corrected and uncorrected distance visual acuity

- Complications

- Patient reported outcomes (PROMs)

- Cost-effectiveness and budget impact

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. The majority of patients suffer from bilateral cataract and while cataract surgery of only one eye is effective in restoring functional vision, second-eye surgery leads to further improvements in health-related quality of life, and is cost-effective. At present, most patients undergo cataract surgery in both eyes on separate days as recommended in national guidelines, referred to as delayed sequential bilateral cataract surgery (DSBCS). An alternative procedure involves operating both eyes on the same day, but as separate procedures, known as immediately sequential bilateral cataract surgery (ISBCS). Our hypothesis is that the clinical effectiveness and quality of life of ISBCS and DSBCS are equivalent, while ISBCS leads to lower costs and better patient

satisfaction.

Study objective

To evaluate the effectiveness and costs of immediately sequential bilateral cataract surgery (ISBCS) compared to delayed sequential bilateral cataract surgery (DSBCS; usual care) in order to determine whether ISBCS is an effective and cost-effective alternative to DSBCS.

Study design

Multicentre randomized clinical trial.

Intervention

Intervention: Bilateral phacoemulsification cataract surgery during a single operating session by a single surgeon (ISBCS). Surgical procedures will be strictly separated with regard to aseptic procedures.
Usual care / comparison: Bilateral phacoemulsification cataract surgery during two operating sessions with a minimum of two weeks apart (DSBCS).

Study burden and risks

Potential benefits of participating in this study (for patients allocated to ISBCS) include less time between surgeries, fewer hospital visits, a faster total recovery period due to simultaneous postoperative care (eye drops) in both eyes and less use of homecare. 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. The main difference during this study is that in ISBCS both eyes are at risk at the same time, while in DSBCS both eyes are exposed to these risks consecutively. Compared to usual care, the extra burden for all patients participating in this study is filling in questionnaires four times during the study, which will take 10 till 30 minutes per time (depending on follow-up time point).

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 with indication for bilateral cataract surgery
- 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 anaesthesia)
- Cognitive or behavioural 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.

Study design

Design

Study type:	Interventional
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):	04-09-2018
Enrollment:	858
Type:	Actual

Ethics review

Approved WMO

Date:	17-05-2018

Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	16-01-2019
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	10-05-2019
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	NCT03400124
CCMO	NL64304.068.17

Study results

Date completed:	10-12-2020
Actual enrolment:	865

Summary results

Trial is onging in other countries