Effectiveness of Periocular drug Injection in CATaract surgery

Published: 27-11-2020
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The objective of this study is to evaluate the effectiveness of different treatments to prevent CME after cataract surgery, using either topical drugs (control group) or intra-/periocular injections (intervention groups).

Ethical review	Approved WMO
Status	Completed
Health condition type	Retina, choroid and vitreous haemorrhages and vascular disorders
Study type	Interventional

Summary

ID

NL-OMON54515

Source
ToetsingOnline

Brief title
EPICAT

Condition

- Retina, choroid and vitreous haemorrhages and vascular disorders

Synonym
macular edema after cataract surgery; cystoid macular edema (CME)

Research involving
Human

Sponsors and support

Primary sponsor: Medisch Universitair Ziekenhuis Maastricht
Source(s) of monetary or material Support: European Society of Cataract and Refractive Surgeons (ESCRS)

Intervention

Keyword: Cataract, Cystoid Macular edema, Periocular injection, Prevention

Outcome measures

Primary outcome

The primary endpoint is the change in central subfield mean macular thickness

(CSMT) at 6 weeks postoperative as compared to the baseline preoperative.

Secondary outcome

The secundary endpoints are:

the incidence of CME;

the incidence of clinically significant macular edema (CSME);

mean corrected distance visual acuity (CDVA);

para- and perifoveal thickness and total macular volume (TMV);

intraocular pressure (IOP);

anterior chamber inflammation;

visionrelated quality of life;

cost-effectiveness.

Study description

Background summary

In Europe, over 4 million cataract surgeries are performed each year. Cystoid macular edema (CME) is a major cause of suboptimal postoperative visual acuity. Topical steroidal and nonsteroidal anti-inflammatory drugs (NSAIDs) are used to prevent CME. In a recent European multicentre study (PREvention of Macular EDema after cataract surgery; PREMED), we demonstrated that the combination of topical corticosteroids and NSAIDs results in the lowest risk of developing CME after cataract surgery. However, noncompliance with eye drops may compromise the effectiveness of treatment. Noncompliance is often unintentional and

related to forgetfulness or incorrect instillation, particularly in the elderly cataract surgery population. Dropless periocular drug delivery during surgery may improve outcomes and cost-effectiveness, and may alleviate the burden on homecare organizations.

Study objective

The objective of this study is to evaluate the effectiveness of different treatments to prevent CME after cataract surgery, using either topical drugs (control group) or intra-/periocular injections (intervention groups).

Study design

The design of this study is a European randomised controlled multicentre trial with a duration of 36 months.

Intervention

All patients will receive phacoemulsification surgery for cataract and placement of a posterior chamber intraocular lens (IOL). All patients in every group will receive an intracameral cefuroxime injection at the end of cataract surgery, according to ESCRS endophthalmitis prophylaxis guidelines.

Patients will receive either:
[group 1:] topical bromfenac 0.09% and topical dexamethasone disodium phosphate 0.1%. Patients will receive bromfenac 0.09% eye drops twice daily starting two days before surgery and continuing 2 weeks postoperatively, dexamethasone disodium phosphate 0.1% eye drops four times daily starting two days before surgery and continuing four times daily during the first postoperative week and one drop less per day every following week.
[group 2:] subconjunctival injection of 10 mg triamcinolone acetonide (TA) during cataract surgery;
[group 3:] intracameral injection of ketorolac tromethamine solution (Omidria; 0.023 mg/mL) during cataract surgery.
[group 4:] subconjunctival injection of 10 mg TA and intracameral injection of ketorolac tromethamine solution (Omidria; 0.023 mg/mL) during cataract surgery.

Study burden and risks

In this study, standard phacoemulsification techniques will be used. Most measurements and examinations are part of the standard of care in patients who need cataract surgery. Only the OCT measurements are not part of the standard of care in all patients. The examinations are non-invasive, cause no side-effects and only take a few minutes to perform. Patients will also be asked to fill out questionnaires about their quality of vision, quality of life and care for cataract surgery twice, which will take about 35minutes.

The follow-up of standard cataract surgery includes one preoperative and two postoperative visits. In this study, one to possibly two extra postoperative visit will be needed. These visits are important to have a baseline of vision and macula compared to postoperative measurements, before CME can occur. For this/these appointement(s), the patient will have to come to the hospital. Side effects of the eye drops or ketorolac/phenylephrine are rare. Because high ocular pressure happens more often after using triamcinolone acetonide subconjunctival, the eye pressure will be measured every postoperative visit. After completion of the study all patients will receive a gift voucher.

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

All patients:

who are undergoing routine phacoemulsification;
who are 21 years or older;
who should be able to communicate properly and understand instructions.

Exclusion criteria

All ophthalmic exclusion criteria are applicable to the study eye only, unless stated otherwise. General exclusion criteria for participation in this study are: patients who already participated with their contralateral eye; combined surgery (e.g. combined phacoemulsification and trabeculectomy); patients with an increased risk of developing cystoid macular edema (CME) in the study eye (e.g. diabetes mellitus, Fuchs' endothelial dystrophy, previous retinal venous occlusion, or a history of uveitis, macular edema, epiretinal membrane, or previous retinal surgery); patients who developed CME after cataract surgery in the contralateral eye; patients with cystoid macular changes in the study eye at baseline; patients with an increased risk of developing perioperative complications; patients with permanent moderate visual impairment in the contralateral eye (decimal visual acuity less than 0.3); patients with a history of steroid induced IOP rise or glaucomatous visual field loss; patients using drugs that reduce or increase the risk of macular edema (e.g., perioculair or intraocular corticosteroid, NSAID, or antivascular endothelial growth factor (VEGF) injection; topical corticosteroid or NSAID use; systemic corticosteroids (>= 20mg prednisolon), methotrexate, biologicals, or acetazolamide), or in the previous 4 months; patients with a contraindication for any of the investigated drugs; patients who are cardiovascular unstable; patients who have a history of hyperthyroidism. Data of subjects without a baseline OCT of sufficient quality will be excluded from analysis. However, these patients cannot be excluded from the study, as they already received (part of) the study medication. In case of perioperative complications (e.g. posterior capsule rupture, anterior vitrectomy, choroidal haemorrhage) data will not be included in the final analysis.

Study design

Design

Study phase:	3
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial

Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Completed
Start date (anticipated):	13-10-2021
Enrollment:	683
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Dexamethasone
Generic name:	Dexamethasone ophthalmic solution
Registration:	Yes - NL outside intended use
Product type:	Medicine
Brand name:	Dexa-POS
Generic name:	Dexamethasone
Registration:	Yes - NL outside intended use
Product type:	Medicine
Brand name:	Omidria
Generic name:	fenylefrine/ketorolac
Registration:	Yes - NL outside intended use
Product type:	Medicine
Brand name:	Triesence
Generic name:	Triamcinolone Acetonide
Registration:	Yes - NL outside intended use
Product type:	Medicine
Brand name:	Yellox
Generic name:	Bromfenac
Registration:	Yes - NL intended use

Ethics review

Approved WMO Date:	27-11-2020
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	18-01-2021
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	31-05-2023
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	12-06-2023
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	14-06-2023
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	21-06-2023
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	19-10-2023
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO	

Date:	14-02-2024
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
EudraCT	EUCTR2019-004890-21-NL
CCMO	NL72427.068.19
Other	volgt

Study results

Date completed: 13-08-2024

Summary results
Trial ended prematurely