Effects of post-operative topical steroid versus intraoperative subconjunctival steroid injection and postoperative miotic on intraocular inflammation following cataract extraction.

Published: 13-06-2006
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Primary Objective: Comparison of incidence of post-cataract extraction ocular inflammation with subconjunctival steroid injection versus traditional eye drops.Secondary Objective: Evaluation of usefulness of physostigmine following cataract surgery…

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Ocular infections, irritations and inflammations
Study type	Interventional

Summary

ID

NL-OMON34332

Source
ToetsingOnline

Brief title
Subconjunctival steroid depot after cataract extraction.

Condition

- Ocular infections, irritations and inflammations

Synonym
inflammation of the eye after cataract surgery

Research involving
Human

Sponsors and support

Primary sponsor: Oogziekenhuis Rotterdam
Source(s) of monetary or material Support: Stichting Wetenschappelijk Onderzoek het Oogziekenhuis Prof. Dr. H. J. Flieringa Postbus 70030;3000 LM Rotterdam

Intervention

Keyword: cataract extraction, post-operative ocular inflammation, steroid eye drops, subconjunctival steroid depot

Outcome measures

Primary outcome

Laser flarecount, examined by laser flarecounter, before operation and on day

21.

Thickness of the macula, examined by OCT, before operation and on day 21.

Secondary outcome

Intraocular pressure on day 1 and 21.

Phaco time and energy.

Number of extra visits due to complaints of post-op irritation.

Number of extra visits due to complaints of reduced visual acuity.

Pain (scaling 1-10) on day 1.

Incidence of anterior synechiae on day 21.

BCVA on day 21.

Study description

Background summary

Cataract extraction is the most frequently performed surgical intervention. A relatively high prevalence of post-op ocular inflammation, needing additional treatment and visits, has prompted the search for a treatment to replace the

traditionally prescribed topical steroids. An subconjunctival steroid depot appears to be the most promising alternative.
The use of miotics after cataract extraction appears to have lost its rationale. Therefore, the efficacy of Eserine will be evaluated.

Study objective

Primary Objective: Comparison of incidence of post-cataract extraction ocular inflammation with subconjunctival steroid injection versus traditional eye drops.
Secondary Objective: Evaluation of usefulness of physostigmine following cataract surgery.

Study design

Randomized.
Group 1 (n=100): subconjunctival depot of betamethasone.
Group 2 (n=100): treatment with traditional dexamethasone eye drops.
Group 3 (n=100): as group 2 plus administration of Eserine.
Group 4 (n=100): as group 1 plus administration of Eserine.

Intervention

Group 1: subconjunctival steroid injection.
Group 2: topical steroids (3x per day during 3 weeks).
Group 3: as group 2 plus Eserine.
Group 4: as group 1 plus Eserine.

Study burden and risks

In order to reduce the risk of anterior uveitis or macular edema, post-op steroids are prescribed. Administration of a single intraoperative injection of betamethasone hardly involves any additional risk, but is expected to reduce the patient*s post-op inconvenience and to increase the efficacy of medication.

In order to reduce the risk of dislocation of the implanted lens, eserine is (still) applied. This can result in temporarily increased irritation of the eye or pain around the eye. Should this study demonstrate that eserine does not reduce the risk of lens dislocation then the use of this medication can be suspended indefinitely.

Contacts

Public

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Cataract extraction indication.
Age > 18 years.
Caucasian.
Informed consent.
Post-op follow-up must be feasible.

Exclusion criteria

Subcapsular posterior cataract (very soft, short phaco time).
Brunescens or mature cataract (hard, long phaco time).
Diabetes mellitus.
Age-related macula degeneration.
History of uveitis.
Glaucoma.
History of steroid response.

Per-operative iris manipulation (e.g. miosis or posterior synechiae).
Pre-operative synechiae anterior.
Systemic steroid medication.
Chemotherapy.
Peroperative contact with vitreous.
Sickle cell anemia.
Corneal complications.
Atopy.
HSV.

Study design

Design

Study phase:	4
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	29-01-2007
Enrollment:	400
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	celestone chronodose
Generic name:	betamethasone
Registration:	Yes - NL outside intended use
Product type:	Medicine
Brand name:	Dexamethasone ratiopharm 1 mg/ml, eye drops

Generic name:	dexamethasone
Registration:	Yes - NL intended use
Product type:	Medicine
Brand name:	eserine
Generic name:	physostigmine salicylate eye cream 1% (magistral formulation)

Ethics review

Approved WMO Date:	13-06-2006
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	19-09-2006
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	30-11-2009
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	01-12-2009
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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	EUCTR2006-001486-41-NL
CCMO	NL11114.078.06