The post-cataract inflammatory reaction with combination therapy of topical steroid and NSAID.

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Evaluation of the inflammatory reaction with NSAID and steroid prophylaxis.

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

Summary

ID

NL-OMON37669

Source
ToetsingOnline

Brief title
Post-cataract topical steroid & NSAID therapy

Condition

- Ocular infections, irritations and inflammations

Synonym
ocular inflammatory reaction

Research involving
Human

Sponsors and support

Primary sponsor: Oogziekenhuis Rotterdam
Source(s) of monetary or material Support: Nuts OHRA

Intervention

Keyword: cataract, flare count, prohylaxis

Outcome measures

Primary outcome

Flare counts at baseline and post-op day 1, 3, 5, 7, 10, 14, 21, 30, 60 and 90.

Secondary outcome

Retinal thickness, visual acuity.

Study description

Background summary

Suppression of the inflammatory activity after cataract extraction may prevent complications. Historically, corticosteroid eye drops have been standard prophylaxis. It is hypothesized that the combination of NSAID and steroid eye drops shows pharmacodynamic synergy.

Study objective

Evaluation of the inflammatory reaction with NSAID and steroid prophylaxis.

Study design

Observational pharmacodynamic.

Study burden and risks

Risks involved are considered to be small. For this part of the study patients are selected by zip-code to minimize travel time to the hospital.

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

- Age > 18 years.
- Caucasian.
- Informed consent.
- Post-op follow-up must be feasible.
- Living at address with zip code of Rotterdam or close vicinity.
- Cataract extraction performed.

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.
- Pre-operative synechiae anterior

- Systemic or topical steroid medication.
- Chemotherapy.
- Sickle cell anemia.
- Corneal complications.
- Keratoconjunctivitis sicca
- Rheumatoid arthritis
- HSV.

Study design

Design

Study phase:	4
Study type:	Observational non invasive
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	24-05-2012
Enrollment:	10
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Dexamethasone ratiopharm
Generic name:	dexamethasone
Registration:	Yes - NL intended use
Product type:	Medicine
Brand name:	Nevanac
Generic name:	nepafenac
Registration:	Yes - NL intended use

Ethics review

Approved WMO Date:	23-12-2011
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	15-05-2012
Application type:	First submission
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	EUCTR2011-006066-40-NL
CCMO	NL39154.078.11