

Subconjunctival steroid depot after cataract extraction

Submission date 28/12/2006	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 28/12/2006	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 05/01/2021	Condition category Eye Diseases	<input type="checkbox"/> Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
OZR-2006-01, NL768, NTR779

Study information

Scientific Title

Subconjunctival steroid depot after cataract extraction

Study objectives

A single subconjunctival Celestone chronodose injection immediately following cataract extraction reduces the incidence of post-operative ocular inflammation when compared with conventional post-operative eye drops therapy.

Post-op administration of eserine does not reduce the incidence of dislocation of the intraocular lens implant any further.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethics approval received from the local medical ethics committee

Study design

Randomised, controlled, parallel group trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Not specified

Study type(s)

Treatment

Participant information sheet

Health condition(s) or problem(s) studied

Cataract

Interventions

Group 1: subconjunctival steroid injection.

Group 2: topical steroids (three times per day during three weeks).

Group 3: as group two plus Eserine.

Group 4: as group one plus Eserine.

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Steroids, Celestone chronodose and Eserine

Primary outcome measure

1. Laser flarecount, examined by laser flarecounter, before operation and on day 21.
2. Thickness of the macula, examined by Optical Coherence Tomography (OCT), before operation and on day 21.

Secondary outcome measures

1. Number of extra visits due to complaints of post-op irritation.
2. Number of patients with macular edema, examined by OCT, on day 21.
3. Intraocular pressure on day one and 21.
4. Number of extra visits due to complaints of reduced visual acuity (miotic wearing off).
5. Pain (scaling one to ten) on day one.
6. Incidence of anterior synechiae (gonioscopic evaluation) on day 21.
7. Best Corrected Visual Acuity (BCVA) using the Early Treatment Diabetic Retinopathy Study (ETDRS) chart on day 21.

Overall study start date

01/01/2007

Completion date

30/06/2008

Eligibility

Key inclusion criteria

1. Cataract extraction indication
2. Aged over 18 years
3. Caucasian - informed consent
4. Post-op follow-up must be feasible

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Not Specified

Target number of participants

400

Total final enrolment

400

Key exclusion criteria

1. Subcapsular posterior cataract (very soft, short phaco time)
2. Brunescens or mature cataract (hard, long phaco time)
3. Diabetes mellitus
4. Age-related macula degeneration
5. History of uveitis
6. Glaucoma
7. History of steroid response
8. Per-operative iris manipulation (e.g. miosis or posterior synechiae)
9. Pre-operative synechiae anterior
10. Systemic steroid medication
11. Chemotherapy
12. Peroperative contact with vitreous
13. Sick cell anemia
14. Corneal complications
15. Atopy
16. Herpes Simplex Virus (HSV)

Date of first enrolment

01/01/2007

Date of final enrolment

30/06/2008

Locations**Countries of recruitment**

Netherlands

Study participating centre

Oogziekenhuis Rotterdam

Rotterdam

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3011 BH

Sponsor information**Organisation**

The Rotterdam Eye Hospital (Oogziekenhuis Rotterdam) (OZR) (The Netherlands)

Sponsor details

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Sponsor type

Hospital/treatment centre

Website

<http://www.oogziekenhuis.nl/>

ROR

<https://ror.org/02hjc7j46>

Funder(s)

Funder type

Research organisation

Funder Name

Stichting Wetenschappelijk Onderzoek het Oogziekenhuis (The Netherlands)

Results and Publications

Publication and dissemination plan

Not provided at time of registration

Intention to publish date**Individual participant data (IPD) sharing plan****IPD sharing plan summary**

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/04/2012	05/01/2021	Yes	No