

Subconjunctival steroid depot after cataract extraction

Submission date 28/12/2006	Recruitment status No longer recruiting	☒ Prospectively registered ☐ Protocol
Registration date 28/12/2006	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 05/01/2021	Condition category Eye Diseases	☐ 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

Protocol serial number
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

Primary study design

Interventional

Study design

Randomised, controlled, parallel group trial

Study type(s)

Treatment

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(s)

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.

Key secondary outcome(s)

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.

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Sex

Not Specified

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

Netherlands

3011 BH

Sponsor information

Organisation

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

ROR

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

Funder(s)

Funder type

Research organisation

Funder Name

Stichting Wetenschappelijk Onderzoek het Oogziekenhuis (The Netherlands)

Results and Publications

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