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Subconjunctival steroid depot after cataract extraction

Submission date	Recruitment status	[X] Prospectively registered
28/12/2006	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
28/12/2006	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
05/01/2021	Eye Diseases	

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

Study design
Randomised, controlled, parallel group trial

Primary study design
Interventional

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. Sickle 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