Does a pre-operative subconjunctival injection of dexamethasone reduce the incidence of proliferative vitreoretinopathy in patients with ablatio retinae?

| Submission date | Recruitment status No longer recruiting | Prospectively registered | | |
|-------------------|---|--|--|--|
| 20/12/2005 | | Protocol | | |
| Registration date | Overall study status | Statistical analysis plan | | |
| 20/12/2005 | Completed | [X] Results | | |
| Last Edited | Condition category | Individual participant data | | |
| 04/11/2010 | Fue Diseases | | | |

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

Protocol serial number

OZR-2001-09; NTR194

Study information

Scientific Title

Study objectives

A pre-operative subconjunctival injection of dexamethasone reduces the incidence of proliferative vitreoretinopathy in patients with ablatio retinae.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Received from the local medical ethics committee

Study design

Randomised double blind, placebo controlled, parallel group trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Rhegmatogenous retinal detachment

Interventions

Pre-operative and post-operative subconjunctival injection of dexamethasone (10 mg) or placebo.

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Dexamethasone

Primary outcome(s)

Incidence of proliferative vitreoretinopathy.

Key secondary outcome(s))

No secondary outcome measures

Completion date

22/01/2005

Eligibility

Key inclusion criteria

- 1. Primary rhegmatogenous retinal detachment
- 2. No previous ablation surgery

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

All

Key exclusion criteria

- 1. Diabetes mellitus
- 2. Systemic steroids
- 3. Steroid eye drops
- 4. Steroid glaucoma responder

Date of first enrolment

01/11/2002

Date of final enrolment

22/01/2005

Locations

Countries of recruitment

Netherlands

Study participating centre Oogziekenhuis Rotterdam

Rotterdam Netherlands 3011 BH

Sponsor information

Organisation

Rotterdam Eye Hospital (Oogziekenhuis Rotterdam) (The Netherlands)

ROR

https://ror.org/02hjc7j46

Funder(s)

Funder type

Research organisation

Funder Name

Foundation of Scientific Research at the Eye Hospital (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 | 01/07/2010 | | Yes | No |