

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

<b>Submission date</b> 20/12/2005	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 20/12/2005	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 04/11/2010	<b>Condition category</b> 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-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

## Secondary study design

Randomised controlled trial

## Study setting(s)

Other

## Study type(s)

Treatment

## Participant information sheet

## 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 measure**

Incidence of proliferative vitreoretinopathy.

**Secondary outcome measures**

No secondary outcome measures

**Overall study start date**

01/11/2002

**Completion date**

22/01/2005

## **Eligibility**

**Key inclusion criteria**

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

**Participant type(s)**

Patient

**Age group**

Adult

**Sex**

Both

**Target number of participants**

40 (Study closed, analysis & publication in progress)

**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)

### **Sponsor details**

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### **Sponsor type**

Hospital/treatment centre

### **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**

### **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?
<a href="#">Results article</a>	results	01/07/2010		Yes	No