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# Intravitreal dexamethasone treatment of bacterial endophthalmitis

| Submission date | Recruitment status | [ ] Prospectively registered |
|---|---|---|
| 20/12/2005 | No longer recruiting | [ ] Protocol |
| **Registration date** | **Overall study status** | [ ] Statistical analysis plan |
| 20/12/2005 | Completed | [ ] Results |
| **Last Edited** | **Condition category** | [ ] Individual participant data |
| 05/11/2008 | Eye Diseases | [ ] Record updated in last year |

**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-2001-18; NTR189

## Study information

**Scientific Title**

**Study objectives**

Intravitreal injection of vancomycin 0.2 mg, gentamycin 0.05 mg, and dexamethasone diphosphate 400 mg reduces tissue damage in patients with bacterial endophthalmitis.

### 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
Post-operative bacterial endophthalmitis

### Interventions
Intravitreal injection of vancomycin 0.2 mg, gentamycin 0.05 mg, and dexamethasone diphosphate 400 mg or placebo.

### Intervention Type
Drug

### Phase
Not Specified

### Drug/device/biological/vaccine name(s)
Vancomycin, gentamycin, dexamethasone diphosphate

### Primary outcome(s)
Vision (ETDRS) after 3, 6 and 12 months, panbacterial polymerase chain reaction (PCR).

### Key secondary outcome(s))
No secondary outcome measures

### Completion date
01/01/2005

## Eligibility

### Key inclusion criteria
1. Post-cataract bacterial endophthalmitis
2. Strong, and increasing, irritation of anterior chamber and/or vitreous during post-operative 8 weeks interval

**Participant type(s)**
Patient

**Healthy volunteers allowed**
No

**Age group**
Not Specified

**Sex**
Not Specified

**Key exclusion criteria**
Antibiotics treatment

**Date of first enrolment**
01/01/2003

**Date of final enrolment**
01/01/2005

# Locations

**Countries of recruitment**
Netherlands

**Study participating centre**
**Oogziekenhuis Rotterdam**
Rotterdam
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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