

Intravitreal dexamethasone treatment of bacterial endophthalmitis

Submission date 20/12/2005	Recruitment status No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 20/12/2005	Overall study status Completed	☐ Statistical analysis plan ☐ Results
Last Edited 05/11/2008	Condition category Eye Diseases	☐ Individual participant data ☐ 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

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