ISRCTN77234772 https://doi.org/10.1186/ISRCTN77234772

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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Treatment

Participant information sheet

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 measure
Vision (ETDRS) after 3, 6 and 12 months, panbacterial polymerase chain reaction (PCR).

Secondary outcome measures
No secondary outcome measures

Overall study start date
01/01/2003

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

Age group
Not Specified

Sex
Not Specified

Target number of participants
150

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)

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