ISRCTN31308983 https://doi.org/10.1186/ISRCTN31308983

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

Submission date
20/12/2005

Registration date
20/12/2005

Last Edited
04/11/2010

Recruitment status
No longer recruiting

Overall study status
Completed

Condition category
Eye Diseases

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr J C van Meurs

Contact details
Oogziekenhuis Rotterdam
Schiedamsevest 180
Rotterdam
Netherlands
3011 BH
+31 (0)10 401 7777
vanMeurs@oogziekenhuis.nl

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
Schiedamsevest 180
Rotterdam
Netherlands
3011 BH
+31 (0)10 401 77 77
info@oogziekenhuis.nl

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?
Results article	results	01/07/2010		Yes	No