

Use of prednisone for choroidal detachment after trabeculectomy

Submission date 14/10/2008	Recruitment status No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 30/10/2008	Overall study status Completed	☐ Statistical analysis plan ☐ Results
Last Edited 30/10/2008	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
0745/02

Study information

Scientific Title
Use of prednisone for choroidal detachment after trabeculectomy: a double-masked randomised controlled trial

Study objectives

To evaluate the treatment with oral prednisone for choroidal detachment after trabeculectomy.

Ethics approval required

Old ethics approval format

Ethics approval(s)

The Ethics Committee of the Federal University of Sao Paulo gave approval on the 27th November 2002.

Primary study design

Interventional

Study design

Double-masked randomised controlled trial

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Choroidal detachment after trabeculectomy

Interventions

Oral prednisone 1 mg/kg daily for 7 days followed by a progressive reduction of 10 mg every 7 days. Patients in the placebo group received similar capsules containing starch for the same duration as the intervention group. Duration of the treatment ranged from 4 to 7 weeks.

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Prednisone

Primary outcome(s)

Choroidal detachment resolution. Indirect ophthalmoscopy and ocular ultrasonography (B-mode) were performed weekly to evaluate the choroidal detachment until total reattachment of the choroid. The main outcome measure was the time elapsed between the detection of detachment and total reattachment of the choroid.

Key secondary outcome(s)

Intra-ocular pressure, evaluated every 5 days.

Completion date

01/12/2005

Eligibility

Key inclusion criteria

1. Both males and females, older than 18 years old
2. Primary open or narrow angle glaucoma submitted to trabeculectomy that developed choroidal detachment
3. Choroidal detachment should be diagnosed during the first two weeks after surgery
4. Choroidal detachment should be exudative by ultra-sound

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Sex

All

Key exclusion criteria

1. Other acute ocular disease
2. Positive Seidel test
3. Choroidal kissing
4. Athalamia
5. Clinical uncontrolled diabetes mellitus or systemic arterial hypertension
6. Hypersensitivity for any of the drugs components on the trial
7. Psychiatric disease
8. Pregnancy

Date of first enrolment

01/02/2003

Date of final enrolment

01/12/2005

Locations**Countries of recruitment**

Brazil

Study participating centre

Federal University of Sao Paulo

Sao Paulo

Brazil

04023-062

Sponsor information

Organisation

Coordination of Improvement of Higher Education (Coordenacao de Aperfeicoamento de Pessoal de Nivel Superior [CAPES]) (Brazil)

ROR

<https://ror.org/00x0ma614>

Funder(s)

Funder type

Government

Funder Name

Coordination of Improvement of Higher Education (Coordenacao de Aperfeicoamento de Pessoal de Nivel Superior [CAPES]) (Brazil)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration