ISRCTN15966680 https://doi.org/10.1186/ISRCTN15966680

Use of prednisone for choroidal detachment after trabeculectomy

Submission date	Recruitment status	[ ] Prospectively registered
14/10/2008	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
30/10/2008	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
30/10/2008	Eye Diseases	[ ] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Augusto Paranhos

Contact details
Federal University of Sao Paulo
Botucatu, 824
Sao Paulo
Brazil
04023-062
augusto.paranhos@uol.com.br

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.

Study design
Double-masked randomised controlled trial

Primary study design
Interventional

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 then 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