

# Use of prednisone for choroidal detachment after trabeculectomy

<b>Submission date</b> 14/10/2008	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 30/10/2008	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 30/10/2008	<b>Condition category</b> Eye Diseases	<input type="checkbox"/> Individual participant data <input type="checkbox"/> 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**  
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

**Secondary study design**

Randomised controlled trial

**Study setting(s)**

Hospital

**Study type(s)**

Treatment

**Participant information sheet****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 measure**

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.

### **Secondary outcome measures**

Intra-ocular pressure, evaluated every 5 days.

### **Overall study start date**

01/02/2003

### **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

### **Age group**

Adult

### **Lower age limit**

18 Years

### **Sex**

Both

### **Target number of participants**

40

### **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)

**Sponsor details**

Ministério da Educação

Anexos I e II - 2º andar

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**Sponsor type**

Government

**Website**

<http://www.capes.gov.br>

**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**

**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