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# Comparative trial of a 0.5% timolol-2% dorzolamide-0.2% brimonidine solution in fixed combination versus Combigan-D® in open angle glaucoma or ocular hypertension

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| **Submission date**<br>09/03/2009 | **Recruitment status**<br>No longer recruiting | [_] Prospectively registered<br>[_] Protocol<br>[_] Statistical analysis plan<br>[_] Results<br>[_] Individual participant data<br>[_] Record updated in last year |
| **Registration date**<br>17/03/2009 | **Overall study status**<br>Completed | |
| **Last Edited**<br>17/03/2009 | **Condition category**<br>Eye Diseases | |

**Plain English summary of protocol**
Not provided at time of registration

## Contact information

**Type(s)**
Scientific

**Contact name**
Dr Leopoldo Baiza-Duran

**Contact details**
Paseo del Norte No. 5255
Fracc. Guadalajara Technology Park
Zapopan
Mexico
45010
+52 (01)33 30014200
drbvista@sophia.com.mx

## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

### Secondary identifying numbers
KKVSCD0208FII

# Study information

### Scientific Title
Multicentre comparative clinical trial of the safety and efficacy of a 0.5% timolol-2% dorzolamide-0.2% brimonidine ophthalmic solution in fixed combination (formulated by Laboratorios Sophia S.A. de C.V.) versus Combigan-D® in open angle glaucoma or ocular hypertension

### Acronym
KOSG

### Study objectives
The hypotensive effect of 0.5% timolol-2% dorzolamide-0.2% brimonidine fixed combination is different from that of Combigan-D® in patients with diagnosis of primary open-angle glaucoma (POAG) and/or ocular hypertension with or without pseudoexfoliation.

### Ethics approval required
Old ethics approval format

### Ethics approval(s)
1. Ethics committee of Fundación Oftalmológica Conde de Valenciana, IAP., approved on the 1st September 2008 (ref: CC-019-2008)
2. Ethics committee of Asociación para Evitar la Ceguera en México, IAP., approved on the 16th July 2008 (ref: 08-36)
3. Ethics committee of Fundación Oftalmólogica Hospital Nuestra Señora de la Luz, approved on the 6th May 2008
4. Ethics committee of Hospital Puerta de Hierro, approved on the 13th June 2009 (ref: 2008/05)
5. Ethics committee of Unidad de Investigación Clínica en Medicina, S.C., approved on the 26th January 2009 (ref: 09-001)

### Study design
Phase III double-blind randomised controlled multicentre trial

### Primary study design
Interventional

### Secondary study design
Randomised controlled trial

### Study setting(s)
Hospital

### Study type(s)
Treatment

### Participant information sheet
Only available to recruiting centres/participants

### Health condition(s) or problem(s) studied
Primary open-angle glaucoma, ocular hypertension

### Interventions
According to a random chart, 50 patients will receive over each eye one drop of a topical ophthalmic solution composed of timolol 0.5%, dorzolamide 2% and brimonidine 0.2% in a fixed-combination formula developed by Laboratorios Sophia S.A. de C.V. every 12 hours. The other 50 patients will be administered one drop of Combigan-D® over each eye every 12 hours. Both medications will be administered during a period of 90 days. All the study articles will be labelled with a non-consecutive code number that is randomly generated by a computer.

The total duration of treatment and the total duration of follow-up for will be 3 months, in both arms.

### Intervention Type
Drug

### Phase
Phase III

### Drug/device/biological/vaccine name(s)
0.5% timolol-2% dorzolamide-0.2% brimonidine solution in fixed combination, Combigan-D®

### Primary outcome measure
Intraocular pressure at 3 months (90 days)

### Secondary outcome measures
1. Visual fields at 3 months (90 days)
2. Ocular surface fluorescein staining at 3 months (90 days)

### Overall study start date
01/01/2009

### Completion date
01/07/2009

## Eligibility

### Key inclusion criteria
1. Patients must have a clinical diagnosis of mild to moderate primary open-angle glaucoma (POAG) with or without pseudoexfoliation and pigmentary dispersion or ocular hypertension
2. Both males and females, aged 18 years or older
3. Patients with intraocular pressure between 21 and 30 mmHg

### Participant type(s)
Patient

### Age group
Adult

### Lower age limit
18 Years

### Sex
Both

### Target number of participants
100

### Key exclusion criteria
1. Patients with one blind eye
2. Patients with visual acuity of 20/40 or worse in either of the two eyes without a justifying cause
3. Patients with a history of any concomitant, active-stage ocular disease except the diseases specified in the inclusion criteria
4. Patients taking any medication, regardless of the route of administration, that decisively interferes with the study results, until 48 hours prior to start of the trial or until a time period in which residual effects could be present
5. Sulfa allergy
6. Patients with history of hypersensibility or any medical situation that contraindicates or makes risky the use of any of the study articles or their compounds under any route of administration as well as any drug or formulation derived from them or related to them
7. Contact lens users
8. Women of childbearing potential who are not using an adequate contraceptive method, as well as pregnant or breast-feeding women
9. Patients with history of cataract surgery with or without intraocular lens (IOL) implant (pseudoaphakia or aphakia) three months or less prior to Day 1 of the trial
10. Patients enrolled in any medical trial out of the Laboratorios Sophia S.A. de C.V. sponsorship within the last 90 days prior to this trial
11. Legally disqualified or mentally disabled patients who cannot sign the informed consent to participate in this trial
12. Patients who cannot comply with the medical appointments or with all the protocol requirements
13. Patients who disagree to participate in this trial
14. Patients with optic disc excavation greater than or equal to 0.8
15. Normal-tension glaucoma patients

### Date of first enrolment
01/01/2009

### Date of final enrolment
01/07/2009

## Locations

### Countries of recruitment
Mexico

### Study participating centre

Paseo del Norte No. 5255
Zapopan
Mexico
45010

# Sponsor information

**Organisation**
Laboratorios Sophia S.A. de C.V. (Mexico)

**Sponsor details**
Paseo del Norte No. 5255
Fracc. Guadalajara Technology Park
Zapopan
Mexico
45010
+52 (01)33 30014200
drbvista@sophia.com.mx

**Sponsor type**
Industry

**Website**
http://www.sophia.com.mx

**ROR**
https://ror.org/00zpf2822

# Funder(s)

**Funder type**
Industry

**Funder Name**
Laboratorios Sophia S.A. de C.V. (Mexico)

# 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