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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

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

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
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)

Primary study design
Interventional

Study design
Phase III double-blind randomised controlled multicentre trial

Study type(s)
Treatment

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(s)
Intraocular pressure at 3 months (90 days)

Key secondary outcome(s)
1. Visual fields at 3 months (90 days)
2. Ocular surface fluorescein staining at 3 months (90 days)

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

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

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)

ROR
https://ror.org/00zpf2822

Funder(s)

Funder type
Industry

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

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration