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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 Cosopt® in open angle glaucoma or ocular hypertension

Submission date 04/11/2008	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 23/12/2008	**Overall study status** Completed	
Last Edited 23/12/2008	**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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
DRTBRII11O6

Study information

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

Acronym
KOEG

Study objectives
The hypotensive effect of 0.5% timolol-2% dorzolamide-0.2% brimonidine fixed combination is different from that of Cosopt® 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)
Ethics Committee of the Institute of Ophthalmology, Hospital La Carlota (Intituto de Oftalmologia Hospital La Carlota), gave approval on the 27th November 2006

Study design
Phase II 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

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 Cosopt® over each eye every 12 hours. Both medications will be administered during a period of 90 days. All the study articles will be labeled with a non-consecutive code number that is randomly generated by a computer.

Intervention Type
Drug

Phase
Phase II

Drug/device/biological/vaccine name(s)
Timolol, dorzolamide, brimonidine, Cosopt®

Primary outcome measure
Intraocular pressure. Duration of follow-up: 3 months (90 days).

Secondary outcome measures
1. Visual fields. Duration of follow-up: 3 months (90 days).
2. Ocular surface fluorescein staining. Duration of follow-up: 3 months (90 days).

Overall study start date
01/01/2007

Completion date
31/05/2007

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
01/01/2007

Date of final enrolment
31/05/2007

Locations

Countries of recruitment
Mexico

Study participating centre
Hidalgo No. 861-A
Guadalajara
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Sponsor information

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

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Sponsor type
Industry

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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