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Comparative clinical trial of Krytantek Ofteno® versus Combigan D® in patients with primary open-angle glaucoma

Submission date 04/04/2008	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol
Registration date 17/07/2008	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 17/07/2008	**Condition category** Eye Diseases	[_] Individual participant data [_] 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

KKVSCD0208FII

Study information

Scientific Title
Comparative clinical trial of the safety and efficacy of Krytantek Ofteno® formulated by Laboratorios Sophia S.A. de C.V. versus Combigan D® in the treatment of patients with primary open-angle glaucoma or ocular hypertension

Acronym
KOEG

Study objectives
There is no difference between the hypotensive effect of Krytantek Ofteno® versus Combigan D® in patients with a 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 approval received from the local ethics committee (Nuestra Señora de la Luz Hospital, Mexico City) on the 20th June 2008.

Study design
Multicentre, prospective, longitudinal, comparative, double-blind clinical trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please contact drbvista@sophia.com.mx to request a patient information sheet

Health condition(s) or problem(s) studied
Primary open angle glaucoma

Interventions
According to the random chart, 44 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 (Krytantek Ofteno®) developed by Laboratorios Sophia S.A. de C.V. each

12 hours. The other 44 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 labeled with a non-consecutive "code number" that is randomly-generated by computer.

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Krytantek Ofteno®, Combigan D®

Primary outcome measure
Intraocular pressure, measured at days 0, 7, 15, 30, 60 and 90. In all days the measurement will be at 8:00 am.

Secondary outcome measures
1. Visual fields, evaluation at at days 0 and 90
2. Ocular surface fluorescein staining, measured at at days 0 and 90

Overall study start date
30/04/2008

Completion date
30/04/2009

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. Patients may be of both masculine or feminine genders and must be 18 years old or older
3. Patients with intraocular pressure between 21 - 30 mmHg

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
88 patients

Key exclusion criteria
1. Patients with one blind eye
2. Patients with visual acuity of 20/40 or worst in any of both eyes without a justifying cause
3. Patients with active stage history of any concomitant ocular disease besides the required one
4. Patients taking any medication, whether topically or by any route of administration, that decisively interferes in the study's results, until 48 hours previous to the day 1 of the trial or until a time period in which residual effects could be present
5. Sulfa allergy patients
6. Patients with history of hypersensibility or any medical situation that contraindicates or makes the using of risky for 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 lenses users
8. Fertile-age women 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 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 under 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 clinical trial
12. Patients who cannot comply with the medical appointments or with all the protocol requirements
13. Patients who refuse to participate in this clinical trial
14. Patients with optic disc excavation equal to 0.8 or more
15. Normal-tension glaucoma patients

Date of first enrolment
30/04/2008

Date of final enrolment
30/04/2009

Locations

Countries of recruitment
Bolivia

Chile

Colombia

Dominican Republic

Ecuador

El Salvador

Guatemala

Honduras

Mexico

Nicaragua

Panama

Peru

Venezuela

Study participating centre
Hidalgo No. 861-A
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Sponsor information

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

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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