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Circadian intraocular pressure, blood pressure and diastolic ocular perfusion pressure with timolol-dorzolamide fixed combination compared with latanoprost in newly-diagnosed glaucoma patients

Submission date 18/07/2007	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 08/08/2007	**Overall study status** Completed	
Last Edited 09/08/2007	**Condition category** Cancer	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Prof Luciano Quaranta

Contact details
Centro per lo studio del glaucoma
Piazzale Spedali Civili 1
Brescia
Italy
25123
+39 (0)30 3995 847
quaranta@med.unibs.it

Additional identifiers

Study information

Scientific Title

Study objectives
To evaluate the short-term effect of Timolol-Dorzolamide Fixed Combination (TDFC), and latanoprost 0.005% on the 24-hour Intraocular Pressure (IOP), ambulatory Blood Pressure (BP), and Diastolic Ocular Perfusion Pressure (DOPP), in newly-diagnosed Primary Open-Angle Glaucoma (POAG) patients.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Institutional Review Board of Clinica Oculistica Università degli studi Brescia (ref: 02/2005/03)

Study design
Randomized, observer-masked, two-treatment, two-period cross-over study.

Primary study design
Interventional

Study type(s)
Not Specified

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

Interventions
Following the monitoring of the baseline or washout IOP and BP all study patients were randomly assigned to receive either one drop of TDFC twice daily (08:00 and 20:00) or one drop of latanoprost once in the evening (20:00).

Twenty-four hour IOP and ambulatory BP were measured at the beginning after the interim washout and at the end of each treatment period, thus obtaining 4 circadian curves. At the time of 24-hour IOP and BP assessments patients were hospitalized, and the drugs were administered by the dosing coordinator of the study according to the protocol.

The IOP was measured every two hours. A calibrated Goldmann applanation tonometer (Haag-Streit, Switzerland) was employed to measure sitting IOP at the slit lamp between 08:00 and 22:00, while supine IOP was measured between 24:00 and 06:00, with the patient in bed, by means of a calibrated handheld electronic tonometer (TonoPen XL; Bio-Rad, USA). At each timepoint, the mean of 3 consecutive readings was calculated.

Ambulatory blood pressure monitoring was recorded by means of an automated portable BP device, TM-2430 (A&D Co, Saitama, Japan). Ambulatory BP monitoring units indirectly measure BP through oscillometric measurement of the vibratory signals associated with blood flow in the brachial artery. The BP device satisfies the recommendation by the British Hypertension Society and Association for Advancement of Medical Instrumentation on accuracy levels for both systolic and diastolic blood pressures. A cuff of appropriate size was placed in the subjects non-dominant arm and BP measurements were taken automatically every 15 minutes between 08:00 to 22:00, and every 30 minutes from 22:00 to 08:00. If a certain reading was not performed properly the

device was programmed to repeat it. The recorded BP values throughout the 24-hour period were later recovered from the recording chip and stored in a personal computer.

During the study BP and IOP readings were monitored in the hospital on two separate days, so as to not influence BP readings by the process of IOP measurements, or by waking the patient during the night for IOP evaluation.
IOP measurements were performed by three well-trained masked observers who were unaware of the treatment assignments; their agreement was previously tested on a pilot sample of 15 patients, resulting in an intraclass correlation coefficient of 0.97 and 0.99 for Tonopen and Goldmann tonometry, respectively.
A comprehensive ocular and systemic examination was performed at baseline and at the conclusion of each phase of the trial, and any ocular or systemic adverse events were noted.

Intervention Type
Other

Phase
Not Specified

Primary outcome(s)
The following were measured at baseline, and at the end of each treatment period:
1. 24-hour IOP
2. Ambulatory BP
3. Calculated DOPP

Key secondary outcome(s))
Adverse events

Completion date
31/12/2005

Eligibility

Key inclusion criteria
We enrolled in the present study consecutive newly diagnosed and previously untreated POAG patients who demonstrated typical optic disc excavation and visual field abnormalities. We included POAG patients older than 45 years with no previous history of ocular surgery or laser.
Additional inclusion criteria were:
1. Open-angle by gonioscopy (Grade III-IV according to Shaffers grading system)
2. Untreated diurnal IOP between 23 and 32 mm Hg (mean of the two highest values recorded in a daytime IOP curve with measurements every 2 hours between 08:00 and 18:00 by a calibrated Goldmann applanation tonometry)
3. Visual acuity 20/40 or better
4. Mean defect >6 dB using the Humphrey 24-2 program (Humphrey Visual Field Analyzer model 745 perimeter, Humphrey Instruments, Inc., USA)
5. No history of allergy to the ingredients of any of the study drugs
6. No history of cardiovascular disease (e.g. arterial hypertension, heart disease, arrhythmia)
7. No concomitant systemic treatment (e.g. beta-blockers, angiotensin-converting enzyme inhibitors) that could modify IOP, or blood pressure.
8. Females were enrolled in the study only if they were postmenopausal or were using contraceptives

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Not Specified

Sex
Not Specified

Key exclusion criteria
See inclusion criteria

Date of first enrolment
01/01/2005

Date of final enrolment
31/12/2005

Locations

Countries of recruitment
Italy

Study participating centre
Centro per lo studio del glaucoma
Brescia
Italy
25123

Sponsor information

Organisation
Clinica Oculistica (Italy)

Funder(s)

Funder type
Government

Funder Name
Ministry of Education, University and Research (Ministero dellUniversità e della Ricerca; MIUR) (Italy)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	Results:	01/07/2006		Yes	No