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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

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

**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
N/A

# 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

### Secondary study design
Randomised controlled trial

### Study setting(s)
Not specified

### Study type(s)
Not Specified

### Participant information sheet

### 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 measure
The following were measured at baseline, and at the end of each treatment period:
1. 24-hour IOP
2. Ambulatory BP
3. Calculated DOPP

### Secondary outcome measures
Adverse events

### Overall study start date
01/01/2005

### 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

### Age group
Not Specified

### Sex
Not Specified

### Target number of participants
27

### 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**
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# Sponsor information

**Organisation**
Clinica Oculistica (Italy)

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**Sponsor type**
Hospital/treatment centre

# Funder(s)

**Funder type**
Government

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

# 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

## Study outputs

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