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Physiological diurnal variability and characteristics of the ocular pulse amplitude with the dynamic contour tonometer

Submission date 01/02/2007	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 01/02/2007	**Overall study status** Completed	
Last Edited 15/01/2021	**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
NL852, NTR866

Study information

Scientific Title

Physiological diurnal variability and characteristics of the ocular pulse amplitude with the dynamic contour tonometer

Study objectives
To study the physiological diurnal variability of the Ocular Pulse Amplitude (OPA) and its correlations with other biophysical parameters.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Prospective randomised study

Primary study design
Interventional

Study type(s)
Screening

Health condition(s) or problem(s) studied
Intraocular measurements, no condition, healthy person

Interventions
A prospective study including fifty-two eyes of twenty-eight healthy subjects (15 female, 13 male) with GAT IntraOcular Pressure (IOP) measurements lower than 22 mmHg. The oral consent was obtained from each patient. The IOP measurements by dynamic contour tonometer (SMT Swiss MicroTechnology, Switzerland) were performed under topical anaesthesia (oxybuprocaine hydrochloride 0.4 mg/ml, Thea Pharma).

The same experienced ophthalmologist performed all the examinations in a non-masked fashion. The measurements were taken on the same day at 9:00 am, 1:00 pm and 4:00 pm. To reduce biases due to prior knowledge of the IOP, the examinations were performed as per this following pattern: two consecutive GAT followed by three consecutive Dynamic Contour Tonometer (DCT) IOP measurements (results are digitally shown).

A ten-minute break was taken between GAT and DCT to minimise a tonographic effect. Only the DCT measurements with quality one and two were taken into account.

The Central Corneal Thickness (CCT), the Blood Pressure (BP) and pulse rate were recorded at 4: 00 pm after the last IOP measurements with Tensoval® blood pressure meter (Hartmann AG, Heidenheim, Germany).

The CCT was measured by ultrasound pachymetry Pachette™ (DGH 500 Technology, Inc, Philadelphia, PA). The mean of five readings was considered for the measurement of CCT. Mean IOP and OPA values were calculated for each time session.

Intervention Type
Other

Phase
Not Specified

Primary outcome(s)
We found that the OPA remained constant during the usual outpatient office hours with a negligible inter-measurement variability.

Key secondary outcome(s))
OPA was significantly correlated with IOP values.

Completion date
09/01/2006

Eligibility

Key inclusion criteria
Healthy participants with intraocular pressure lower than 22 mmHg measured by Goldmann Applanation Tonometry (GAT).

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Not Specified

Sex
All

Total final enrolment
28

Key exclusion criteria
1. History of previous ocular trauma, refractive or intraocular surgery and corneal surface diseases as well as contact lens wearers
2. Corneal astigmatism higher than 3.00 diopters and/or ametropia higher than 6.00 diopters
3. Use of systemic medications which could interfere with blood pressure or pulse rate

Date of first enrolment
05/01/2006

Date of final enrolment
09/01/2006

Locations

Countries of recruitment

Belgium

Netherlands

Study participating centre
Department of Ophthalmology
Brussels
Belgium
1100

Sponsor information

Organisation
Clinique Université St. Luc (UCL) (Belgium)

ROR
https://ror.org/03s4khd80

Funder(s)

Funder type
Other

Funder Name
Not provided at time of registration

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	01/12/2007	15/01/2021	Yes	No