Intraocular pressure of patients with normal tension glaucoma in sitting and side-lying positions using the Goldmann applanation tonometer

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The primary objective is to assess the IOP and MAP in sitting and side lying position in healthy subjects and in patients with NTG.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Glaucoma and ocular hypertension
Study type	Observational non invasive

Summary

ID

NL-OMON41843

Source
ToetsingOnline

Brief title
IOP study

Condition

- Glaucoma and ocular hypertension

Synonym
high intra oculair pressure

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: glaucoma, intra oculair pressure, side-lying position

Outcome measures

Primary outcome

The primary objective is assess the intraocular pressure and mean arterial

pressure in sitting and side lying position in healthy subjects and in patients

with NTG.

Secondary outcome

Central corneal thickness will also be measured.

Study description

Background summary

Primary open angle glaucoma (POAG) is a gradually progressive optic neuropathy, resulting in irreversible visual field loss. Elevated intraocular pressure (IOP) remains the most important known risk factor for progression of glaucoma. The IOP level and fluctuation seems to play a role in the disease development and progression, even in cases with statistically normal pressures. The average diurnal IOP, the peak diurnal IOP and the daily fluctuation of IOP were each shown to be an independent risk factor for glaucoma progression [1]. Diurnal IOP fluctuation is greater in glaucomatous patients than in normal patients [2]. In most individuals, including glaucoma suspects and glaucoma patients, lying down causes a substantial increase in the IOP [1,2]. This is highly relevant because people spend about one third of their lives lying down [1]. Therefore, it seems very important that besides office measurement of IOP in the sitting position, measurements of IOP when lying down are done as well.

Numerous studies evaluated the difference in IOP between sitting and lying down [2]. However, most of these studies used pneumatic tonometry. Quaranta et al. [3] showed that the untreated mean supine IOP with Perkins applanation tonometry is not higher at night when compared to daytime sitting Goldmann applanation tonometry. However, Perkins applanation tonometry in this study is compared to Goldmann applanation tonometry. Glovinsky et al. [1] showed that the IOP (measured by Goldmann applanation tonometry) when lying down was significantly higher than the mean maximal diurnal sitting IOP among untreated

subjects with ocular hypertension or patients with optic discs suspicious for glaucoma. Over 20% had an IOP increase of 6 mmHg or more when lying down. Tuskahara et al. [4] found a 32% greater mean IOP rise (from sitting to supine position) in patients with normal tension glaucoma (NTG) when compared to those with primary open-angle glaucoma.

A new system for IOP measurement by slit lamp mounted Goldmann applanation tonometer in the side lying position was developed by Dr Y. Glovinsky in the Sheba Medical Centre in Israel. The purpose of this study is to measure the IOP in sitting and side lying position in patients with NTG, using the device developed by Dr Y. Glovinsky.

Also the blood pressure will be measured digitally in the sitting and side lying position. Ocular perfusion pressure (OPP) is defined as the mean arterial pressure (MAP) minus the IOP. Low OPP is a risk factor for the development and progression of glaucoma. Low OPP is related to decreased MAP, increased IOP or both [5]. In this study we want to measure the IOP in patients with NTG in the sitting and side lying position and measure the blood pressure to calculate ocular perfusion pressure. These measurements are of clinical relevance because a higher IOP at night together with a low diastolic blood pressure will alter perfusion of the optic nerves.

Study objective

The primary objective is to assess the IOP and MAP in sitting and side lying position in healthy subjects and in patients with NTG.

Study design

A prospective, single center, diagnostic pilot study.

Study burden and risks

The examination will take 10-15 minutes. First, the participant will be asked to sit down in a chair. One drop of oxybuprocaine (4 mg/ml) combined with fluorescine will be instilled in both eyes and the IOP will be measured using a Goldman applanation tonometer. Then, the blood pressure will be measured digitally. Secondly, the participant will be asked to lie down on a bed in side lying position. After 5 minutes, the IOP and blood pressure will be measured again while the participant is still in side lying position. Both IOP measurements will be performed with the same tonometer. Finally, the CCT will be measured, using a pachymeter. All measurements will be performed by an ophthalmologist or ophthalmologist resident.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

•Male or female heathy subjects > 18 years of age who have signed an Informed Consent.
•Male or female patients with NTG (according to the Nederlands oogheelkundig gezelschap (NOG)-guidelines for NTG) at the time of inclusion:
.History of peak intra-ocular pressure (IOP) < 22 mm Hg without treatment (diurnal tension curve).

Exclusion criteria

See also protocol page 8, 4.3

Study design

Design

Study phase:	3
Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	10-04-2015
Enrollment:	80
Type:	Actual

Ethics review

Approved WMO

Date:	27-02-2015
Application type:	First submission
Review commission:	METC Amsterdam UMC

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL50736.018.14