Externally induced eye pressure during sleep.

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To demonstrate that externally induced increases in subpalpebral pressure (SPP) relate to clinically significant increases in IOP, and to determine posture dependency of SPP. To determine the effects of protective goggles on SPP under these...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Glaucoma and ocular hypertension
Study type	Interventional

Summary

ID

NL-OMON33394

Source
ToetsingOnline

Brief title
IOP during sleep.

Condition

- Glaucoma and ocular hypertension

Synonym
Intraocular pressure.

Research involving
Human

Sponsors and support

Primary sponsor: Oogziekenhuis Rotterdam
Source(s) of monetary or material Support: Stichting Wetenschappelijk Onderzoek Oogziekenhuis Prof. Dr. Flieringa (SWOO)

Intervention

Keyword: Intraocular pressure, Sleep, Subpalpebral pressure

Outcome measures

Primary outcome

IOP and SPP.

Secondary outcome

NA

Study description

Background summary

Glaucoma is the commonest cause of irreversible blindness in the world. An increased intra-ocular pressure (IOP) is the most important risk-factor for the development (and progression) of glaucoma. Even without proven increases in IOP may glaucoma come about or become worse. It is currently unknown how much the IOP is affected during sleep when the pillow presses against the face and eyelids. The pressure increases will be measured under the eyelids when subjects lie horizontally with their heads resting normally on their own pillows, assuming a posture similar to during sleep.

Study objective

To demonstrate that externally induced increases in subpalpebral pressure (SPP) relate to clinically significant increases in IOP, and to determine posture dependency of SPP. To determine the effects of protective goggles on SPP under these conditions.

Study design

Experimental study.

Intervention

wearing of protective spectacles

Study burden and risks

Participants do not benefit from cooperating. Risks are considered to be small, the burden is moderate.

Contacts

Public
Oogziekenhuis Rotterdam

Schiedamse Vest 180
3011 BH Rotterdam
Nederland
Scientific
Oogziekenhuis Rotterdam

Schiedamse Vest 180
3011 BH Rotterdam
Nederland

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

- Age >18 years.
- Informed consent.

Exclusion criteria

- History of IOP-reducing surgical intervention.

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	15-01-2010
Enrollment:	20
Type:	Actual

Ethics review

Approved WMO Date:	06-05-2009
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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	NL26971.078.09