Risk factors for glaucoma in musicians

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Primary Objective:* To study the impact of playing wind instruments for the development of OHT and (progression of) glaucoma.Secondary Objective(s): * To study the risk factors for the development of OHT and glaucoma in professional musicians.* To...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Eye disorders NEC
Study type	Observational non invasive

Summary

ID

NL-OMON36984

Source ToetsingOnline

Brief title Glaucoma-musicians

Condition

• Eye disorders NEC

Synonym glaucoma, increased eye pressure

Research involving Human

Sponsors and support

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

Intervention

Keyword: eye disease, glaucoma, impaired visual acuity, musicians

Outcome measures

Primary outcome

Primary Objective:

* To study the impact of playing wind instruments for the development of OHT

and (progression of) glaucoma.

Secondary outcome

Secondary Objective(s):

* To study the risk factors for the development of OHT and glaucoma in

professional musicians.

* To study the prevalence of visual problems and eye diseases in professional

musicians.

Study description

Background summary

Glaucoma is a possibly blinding condition for which early detection and treatment is warranted. Playing wind instruments, especially high resistance wind instruments (oboe/bassoon/trumpet/French horn), may predispose the onset of ocular hypertension (OHT) and glaucoma by increasing intraocular pressure (IOP). However, evidence concerning the exact relationship between the playing of wind instruments and the onset of OHT or glaucoma is scarce and the impact of playing wind instruments on the progression of the disease in patients who already have glaucoma is not known. Additionally, the magnitude of musicians who are at risk is not known. Identifying musicians who are at risk for glaucoma or already have glaucoma and play wind instruments for many hours per week will promote early and efficient treatment of patients in this particular population. Studying the amount and mechanism of IOP increase of musicians while playing their different instruments will lead to a better understanding of which musicians are at risk for developing OHT and (progression of) glaucoma. If the hypothesis that wind musicians have a higher risk of OHT and glaucoma can be proven, the development of a screening program for early detection and treatment of OHT and glaucoma in wind instrument players can be useful. Additionally, there is some evidence that visual and other eye problems may

occur quite frequently among musicians in orchestras. For example, uncorrected refractive errors may lead to early fatigue, painful eyes and headaches. This has not been investigated in the Netherlands.

With the contact lens device for continuous IOP monitoring, IOP can be monitored in ambulatory mode and during normal activities (including studying at home with their instrument, rehearsals, rest, meals, and the sleep period), in the habitual position of the participants. This will give the researchers important information concerning the frequency of IOP peaks during the day and night, from which valuable feedback and advice can be given to the study participants concerning their risk for the development or progression of glaucoma.

Study objective

Primary Objective:

* To study the impact of playing wind instruments for the development of OHT and (progression of) glaucoma.

Secondary Objective(s):

* To study the risk factors for the development of OHT and glaucoma in professional musicians.

* To study the prevalence of visual problems and eye diseases in professional musicians.

Study design

Observational study.

Study burden and risks

There are no risks involved for the participants. Screening for OHT and glaucoma together with other eye complaints may be very beneficial for the early diagnosis and treatment of affected individuals and awareness of group related problems, if applicable.

However, in case an unsuspected eye disease is diagnosed during screening, this may be a burden to the patient and may cause further difficulties if the change to take out a policy on health insurance is hampered.

There are no substantial risks expected for the participants who agree to undergo IOP monitoring over a 24 hour period with a sensing contact lens, which is pure silicone with an oxygen plasma surface treatment to create a highly hydrophilic interface between the sensor and all tissues in contact. The device provides a leven of oxygen permeability equal to or greater than the recommended boudaries of extended wear to avoid corneal hypoxia. This means that the cornea is as protected as possible from metabolic stress during the monitoring period.

A possible burden may be that with the use of the sensing contact lens, an antenna is placed round the eye, which is connected to a portable recorder through a thin flexible data cable. The recorder is placed on the chest. The antenna is visible for other people.

Contacts

Public Selecteer

P. Debyelaan 25 6202 AZ Maastricht NL **Scientific** Selecteer

P. Debyelaan 25 6202 AZ Maastricht NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

All full time or part time professional players of participating symphony or wind orchestras

Exclusion criteria

Difficulty in reading or speaking Dutch

Study design

Design

Study type: Observational non invasive	
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	01-05-2010
Enrollment:	120
Туре:	Actual

Ethics review

Approved WMO Date:	10-02-2010
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	19-09-2011
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

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 CCMO ID NL25853.068.09