Longitudinal evaluation of hearing loss and other hearing complaints in professional musicians

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Study the long term effects of frequent exposure to high sound levels on hearing status in orchestral musicians. To assess the hearing condition, several clinically available tests will be used, but for the assessment of diplacusis a new test is...

Ethical reviewApproved WMOStatusRecruitment stoppedHealth condition typeHearing disorders

Study type Observational non invasive

Summary

ID

NL-OMON48954

Source

ToetsingOnline

Brief title

Long term hearing in musicians

Condition

Hearing disorders

Synonym

Hearing impairment, Music induced hearing loss

Research involving

Human

Sponsors and support

Primary sponsor: Klinische en Experimentele Audiologie

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

Intervention

Keyword: diplacusis, Hearing, long term change, Professional musicians

Outcome measures

Primary outcome

Long-term effects will be assessed in terms of changes in pure tone audiograms, speech-reception threshold in noise, OAE-grams, subjective and objective tinnitus perception, subjective judgement of suffering from diplacusis, and objective diplacusis measures in professional musicians in a period of 12 years.

Secondary outcome

Reference values for diplacusis at 500, 1000, 4000 and 6000 Hz (means and standard deviations) and reproducibility of the test will be assessed for normal-hearing listeners.

Study description

Background summary

Exposure to excessive noise can contribute to temporary or permanent threshold shifts, where also temporal threshold shifts may lead to permanent hearing loss if the ear has not given change to recover. Although music is perceived as pleasant sounds, frequent and loud exposure to music also carries risk of damage to the auditory system, which is considered equally high as the risk due to noise exposure. Professional musicians whose job exposes them to excessively high sound levels during orchestral ensembles, trainings and individual practice, are therefore at risk of developing hearing loss, known as music induced hearing loss.

Study objective

Study the long term effects of frequent exposure to high sound levels on hearing status in orchestral musicians. To assess the hearing condition,

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several clinically available tests will be used, but for the assessment of diplacusis a new test is required, that has been developed recently and still needs validation. An additional objective of this study is to validate the diplacusis test and assess its reproducibility in normal hearing listeners, before the diplacusis test will be applied in the main study on orchestral musicians.

Study design

This study is designed as a prospective, observational study divided in two parts; first the validation and reproducibility of a new diplacusistest (N=18). The second part (N=45) is the part where the hearing of professional musicians is monitored and changes over a period of 10 - 12 years are researched.

Study burden and risks

The risk of participating in this study is negligible since the tests that will be executed are similar or equal to those used in clinical practice. The participant*s main burden is the time it takes to visit the AMC, which will be only one hour for part 1 and two hours for part 2. The participants take part once in the study. Hence, the burden of the participants is minimal.

Contacts

Public

Selecteer

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Scientific

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Trial sites

Listed location countries

Netherlands

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Eligibility criteria

Age

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

Inclusion criteria

Normal hearing participants

- Aged between 18-75 years old
- No reports of tinnitus
- Hearing thresholds of 15 dB HL or better at octave frequencies between 0.25 and 8 kHz of both ears; Musicians:
- Participants must have previously participated in the study conducted by E.J.M.Jansen in 2005 * 2006.
- Currently employed as professional musician

Exclusion criteria

If the subject for whichever reason cannot participate in the test. Examples include problems with concentration.

Study design

Design

Study type: Observational non invasive

Intervention model: Other

Allocation: Non-randomized controlled trial

Masking: Open (masking not used)

Control: Active

Primary purpose: Prevention

Recruitment

NL

Recruitment status: Recruitment stopped

Start date (anticipated): 07-11-2018

Enrollment: 63

Type: Actual

Ethics review

Approved WMO

Date: 21-06-2018

Application type: First submission

Review commission: METC Amsterdam UMC

Approved WMO

Date: 07-05-2019

Application type: Amendment

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 NL65018.018.18