# 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...

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| **Ethical review** | Approved WMO |
| **Status** | Recruitment stopped |
| **Health condition type** | Hearing 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,

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

# 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

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|---|---|
| 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

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| 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 |