# Detection of Gaps in Auditory Stimuli by tinnitus patients and matched controls

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To test the hypothesis, which states that gap detection is impaired in tinnitus.

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| **Ethical review** | Approved WMO |
| **Status** | Recruitment stopped |
| **Health condition type** | Hearing disorders |
| **Study type** | Observational non invasive |

## Summary

### ID

NL-OMON37138

**Source**
ToetsingOnline

**Brief title**
Gap detection in tinnitus

### Condition

- Hearing disorders

**Synonym**
ringing in the ears, tinnitus

**Research involving**
Human

### Sponsors and support

**Primary sponsor:** Universitair Medisch Centrum Groningen
**Source(s) of monetary or material Support:** Dorhout Mees Familiestichting

### Intervention

**Keyword:** Gap detection, Tinnitus

## Outcome measures

### Primary outcome

The gap detection test results in a minimum audible gap that a subject can hear. This minimum audible gap is referred to as the gap detection threshold. The main study outcome is the difference between the gap detection thresholds of both subject groups.

### Secondary outcome

A secondary hypothesis is that gap detection in humans is more impaired at sound frequencies close to the tinnitus frequency as compared to frequencies that are further away. The relation between gap detection impairment and the tinnitus frequency is a secondary outcome of this study.

# Study description

### Background summary

Tinnitus is a phantom sound percept. Subjects with tinnitus continuously hear a sound that is not related to an acoustical source. Animal models of tinnitus have suggested that tinnitus is associated with impaired gap detection. It is unknown whether humans with tinnitus have impaired gap detection. The hypothesis of this research is that human subjects with tinnitus will show impaired performance on a gap detection test. A gap detection test is a hearing test in which subjects have to identify brief gaps (pauses) in auditory stimuli. The ability to hear the silent pause is hypothesized to be impaired in tinnitus subjects. If the hypothesis is true, this research will provide an important validation of the relevance of animal models of tinnitus to humans. In addition, then the gap detection test may be a possible diagnostic test for tinnitus.

### Study objective

To test the hypothesis, which states that gap detection is impaired in tinnitus.

### Study design

Three groups of subjects will be included. The first group hears tinnitus. The second group hears no tinnitus. This is a control group that is matched to the tinnitus group with respect to age and hearing loss. The third group has no hearing loss and has no tinnitus.

### Study burden and risks

The total testing time per subject is maximally 6 hours, including breaks. During these 6 hours, subjects perform gap detection tests. This testing requires concentration of the subject, and is therefore fatiguing. Therefore, frequent breaks will be included, and the testing time will be distributed over 2 or 3 sessions, with one session per day. Participation in this study, offers no known risk to the participants.

## 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

- adults, age>18 years
- tinnitus (group 1) or no tinnitus (group 2);- adults, age 18- reference group (healthy subjects)

### Exclusion criteria

- a psychiatric condition needing treatment from a psychiater

## 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: | Diagnostic |

### Recruitment

NL

| | |
|---|---|
| Recruitment status: | Recruitment stopped |
| Start date (anticipated): | 09-12-2012 |
| Enrollment: | 70 |
| Type: | Actual |

## Ethics review

Approved WMO

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| Date: | 20-11-2012 |

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| Application type: | First submission |
| Review commission: | METC Universitair Medisch Centrum Groningen (Groningen) |
| Approved WMO Date: | 25-01-2013 |
| Application type: | Amendment |
| Review commission: | METC Universitair Medisch Centrum Groningen (Groningen) |

# 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 | NL42134.042.12 |