# Visualizing tinnitus with fMRI.

Published: 08-09-2010 Last updated: 30-04-2024

Primary: To find out which areas in the brain play a part in the maintenance of tinnitus, and what the roles of those areas are. This will be done using BOLD response fMRI imaging.Secondary: 1. To find out which areas in the brain play a part in the...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Aural disorders NEC
Study type	Observational non invasive

# **Summary**

### ID

NL-OMON34095

**Source** ToetsingOnline

**Brief title** Visualizing tinnitus with fMRI.

# Condition

- Aural disorders NEC
- Neurological disorders NEC

**Synonym** ringing in the ears

**Research involving** Human

# **Sponsors and support**

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

### Intervention

Keyword: fMRI, neuromodulation, tinnitus

1 - Visualizing tinnitus with fMRI. 2-05-2025

#### **Outcome measures**

#### **Primary outcome**

The main fMRI study parameter is the number of active voxels in the auditory cortex and the inferior colliculus. The amount of active voxels is a measure for the amount of activation caused by the application of the stimuli. The number of voxels is determined by comparing both tinnitus matching and non-matching stimuli to the silence.

#### Secondary outcome

A secondary fMRI study parameter is the number of active voxels in other areas of the brain. The AC and IC are the most important, but not the only neural correlates of tinnitus. Activity found in other regions of the brain is also taken into account for further analysis.

# **Study description**

#### **Background summary**

Tinnitus is often defined as the perception of a tone without the presence of an external stimulus. About 10% of the Western adult population suffers from tinnitus and with about 1% of the population the tinnitus seriously interferes with the patients\* lifes. Neuromodulation is a promising treatment for tinnitus, but is not used in the Netherlands so far. In order for neuromodulation to be successful it should be clear where in the brain the neural correlates of tinnitus are. However, the pathophysiology of tinnitus is still greatly unknown. Therefore in this study the brain areas that are suspected to be neural correlates of tinnitus will be visualized with fMRI. The focus with the fMRI measurements will be on the auditory cortex and the inferior colliculus.

#### **Study objective**

Primary:

To find out which areas in the brain play a part in the maintenance of tinnitus, and what the roles of those areas are. This will be done using BOLD response fMRI imaging.

Secondary:

1. To find out which areas in the brain play a part in the development of tinnitus.

2. To assess the theoretical potential of neuromodulation as a therapy for tinnitus.

#### Study design

This is a case-control observational study comparing processing of sound in tinnitus patients with normal hearing subjects and with hearing impaired non-tinnitus subjects.

#### Study burden and risks

Participating subjects are asked to fill out three questionnaires which will take approximately 15 minutes. Furthermore they are asked to travel to the FC Donders Institute (Nijmegen) once. There they will undergo a combined fMRI scan with a duration of about 1 hour. So the individual study duration will be 1,5 hours. There is no individual benefit for the subjects participating in the study. There are no risks associated with the study, nor are there any harmful aspects with respect to participating.

# 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**

General:

- Men and women;

Tinnitus patients:

- Unilateral tinnitus;
- Perception of a tone;
- Tinnitus perception for more than 1 year;
- Unchanged tinnitus perception (pitch, amplitude, side) for more than 6 months.
- Hearing impaired non-tinnitus:

- Perceptive hearing impairment

# **Exclusion criteria**

General:

- Age < 18 years;
- MRI contraindications;
- Claustrophobia;
- Ear inflammation;
- Other ear diseases like acoustic neuroma;
- Diagnosed neurological or psychiatric disease;
- Conductive hearing impairment.

Tinnitus patients:

- Perception of noise;
- Pulsatile tinnitus.

Normal hearing subjects:

- Conductive hearing impairment;
- Use of hearing aids;
- (history of) Menières disease;

- (history of) tinnitus perception.

- Hearing impaired non-tinnitus:
- Conductive hearing impairment;
- (history of) Menières disease;
- (history of) tinnitus perception.

# Study design

### Design

Primary purpose: Basic science		
Masking:	Open (masking not used)	
Allocation:	Non-randomized controlled trial	
Intervention model:	Other	
Study type:	Observational non invasive	

### Recruitment

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NL	
Recruitment status:	Recruiting
Start date (anticipated):	12-10-2010
Enrollment:	72
Туре:	Actual

# **Ethics review**

Approved WMO	
Date:	08-09-2010
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

# **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 NL32562.091.10