

# Functional Magnetic Resonance Imaging of the central auditory system in tinnitus patients and healthy controls.

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The proposed study is designed to investigate the neural substrates of tinnitus using functional Magnetic Resonance Imaging (fMRI). The study is part of the diagnostic and research program \*Diagnosis and treatment of tinnitus with emphasis on...

|                              |                            |
|------------------------------|----------------------------|
| <b>Ethical review</b>        | Approved WMO               |
| <b>Status</b>                | Recruitment stopped        |
| <b>Health condition type</b> | Hearing disorders          |
| <b>Study type</b>            | Observational non invasive |

## Summary

### ID

NL-OMON30933

### Source

ToetsingOnline

### Brief title

fMRI of auditory processing in tinnituspatients

### Condition

- Hearing disorders

### Synonym

ringing in the ears, tinnitus

### Research involving

Human

### Sponsors and support

**Primary sponsor:** Universitair Medisch Centrum Utrecht

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

## Intervention

**Keyword:** fMRI, hyperactivity, Tinnitus, Tonotopy

## Outcome measures

### Primary outcome

differences in haemodynamic response in the tinnitus group as compared to the control groups.

### Secondary outcome

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## Study description

### Background summary

Tinnitus is the perception of meaningless sound in the absence of an external or internal acoustic stimulus (Lockwood et al., 1998; Melcher et al., 2000; Henry et al., 2005; Bauer and Brozoski, 2006). It affects 7 to 19 % of the adult population and it prevents 1% from leading a normal life (Chung et al., 1984; Coles, 1984; Davis, 1989; Davis and Rafaie, 2000; Nondahl et al., 2002; Henry et al., 2005). 80% of tinnitus patients have accompanying observed hearing loss, induced by aging or by noise (Stouffer and Tyler, 1990; Lockwood et al., 2002; Nondahl et al., 2002; Eggermont, 2003; Heller, 2003; Schwaber, 2003; Crummer and Hassan, 2004; Eggermont and Roberts, 2004; Davis and Rafaie, 2000). Despite the high prevalence and morbidity of tinnitus, the pathophysiology of the disorder is poorly understood. It is thought that tinnitus is the result of functional reorganization of auditory neural pathways and tonotopic maps of the central auditory system following peripheral receptor damage. However, little is known about the exact neural abnormalities underlying tinnitus. One possible theory on the neural correlates of tinnitus includes increased spontaneous discharge rate of neurons in auditory cortex and auditory brainstem, and increased synchronization of spontaneous activity of several cortical neurons (Eggermont and Roberts, 2004). The mechanism underlying an increase of spontaneous discharge rate and synchronization is thought to be reduced (lateral) inhibition which is the consequence of the decreased output from damaged cochlear regions. There are only few human imaging studies on tinnitus and these studies confirmed the correlation of increased activity with the tinnitus percept (Lockwood et al., 1998; Giraud et al. 1999; Melcher et al.

2000).

### **Study objective**

The proposed study is designed to investigate the neural substrates of tinnitus using functional Magnetic Resonance Imaging (fMRI). The study is part of the diagnostic and research program \*Diagnosis and treatment of tinnitus with emphasis on rehabilitation and plasticity\* of the department of Otorhinolaryngology (ORL) of the University Medical Center Utrecht.

The aim of this study is to compare the activation in the central auditory system in tinnitus patients with the normal system of healthy controls. The hypothesis is the presence of abnormally high spontaneous activity in the auditory cortical areas in tinnitus patients. More specifically, we will investigate the tonotopic maps of the primary and secondary auditory cortex since the hyperactivity is likely to occur in the specific frequency band of the tinnitus sound. For the experimental conditions, we will use acoustic stimuli consisting of different frequencies to stimulate the different tonotopic maps.

### **Study design**

Observation study using 1 patient group and 2 control groups.

### **Study burden and risks**

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## **Contacts**

### **Public**

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## Trial sites

### Listed location countries

Netherlands

## Eligibility criteria

### Age

Adults (18-64 years)

Elderly (65 years and older)

### Inclusion criteria

For all 3 groups:

- Age > 18 years old
- right-handedness, i.e. a score of >14 point on the Edinburgh Handedness Inventory (Oldfield, 1971)
- written informed consent ;Specifically for the tinnitusgroup:
- unilateral tonal tinnitus;Specifically for the controlgroup of hearing impaired subjects:
- a hearing threshold of > 25 dBHL on 3 or more frequencies of the standard audiogram

### Exclusion criteria

For all 3 groups:

- neurological or mental disorders
- metal implants
- drug or alcohol abuse during a period of 6 months prior to the experiment
- pregnancy
- claustrophobia
- use of medication which might have an effect on the brain ;For the two control groups:
- a positive answer on a question of the medical screening questionnaire (see appendix 5)

## 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:    | Basic science                   |

## Recruitment

|                           |                     |
|---------------------------|---------------------|
| NL                        |                     |
| Recruitment status:       | Recruitment stopped |
| Start date (anticipated): | 25-04-2008          |
| Enrollment:               | 54                  |
| Type:                     | Actual              |

## Ethics review

|                    |                  |
|--------------------|------------------|
| Approved WMO       |                  |
| Date:              | 04-09-2007       |
| Application type:  | First submission |
| Review commission: | METC NedMec      |

## 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     | NL18257.041.07 |