

# Evaluation of the Sensorineural Acuity Level test as a diagnostic test for triage purposes

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Design an audiometric method that:- meet the requirements for triage- is relatively flexible according to the criteria for maximum sound level in the test environmentThe main advantages of this method for the hearing aid practice are:- less chance...

<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-OMON33206

### Source

ToetsingOnline

### Brief title

Evaluation of the SAL test for triage

### Condition

- Hearing disorders

### Synonym

hearing impaired, hearing loss

### Research involving

Human

### Sponsors and support

**Primary sponsor:** Stichting Audicienregister

**Source(s) of monetary or material Support:** Stichting Audicienregister

## Intervention

**Keyword:** audiometry, diagnostic, hearing loss, screening

## Outcome measures

### Primary outcome

- is the adapted audiometric test method applicable in practice
- does the test method meet the requirements for triage

### Secondary outcome

air-bone gap as a function of the frequency

## Study description

### Background summary

Results from a previous study (AZOS project) show that the quality of the audiometry practiced by the hearing aid dispenser is not always according to the standard requirements. This problem is largely caused by the measuring conditions in the hearing aid practice. The hearing tests are not always carried out in a test booth that meets the requirements for screening audiometry. As a consequence, hearing tests are often carried out in an environment with too much noise. This will influence the measuring results obtained and subsequently also the diagnosis of hearing loss.

### Study objective

Design an audiometric method that:

- meet the requirements for triage
- is relatively flexible according to the criteria for maximum sound level in the test environment

The main advantages of this method for the hearing aid practice are:

- less chance on errors during measurement
- unambiguous interpretation of the criteria for referral

### Study design

In phase 1, the audiometric test method will be tested by carrying out the SAL test on 200 patients in the audiologic centre of the Academic Medical Centre

(Amsterdam). During evaluation it has to show if the test method is applicable in practice (proof of concept). If the test method proves to be suitable then the study will be extended to a multi-centre study. The aim in phase 2, is to investigate the implementation of the method in the hearing aid practice.

### **Study burden and risks**

N/A

## **Contacts**

### **Public**

Stichting Audicienregister

Reitseplein 1  
5000 LG Tilburg  
Nederland

### **Scientific**

Stichting Audicienregister

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## **Trial sites**

### **Listed location countries**

Netherlands

## **Eligibility criteria**

### **Age**

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

### **Inclusion criteria**

- 18 years of age or older

- voluntarily
- able to give informed consent

## Exclusion criteria

under 18 years of age

## Study design

### Design

**Study type:** Observational non invasive

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Diagnostic

### Recruitment

NL

Recruitment status: Recruitment stopped

Start date (anticipated): 09-06-2009

Enrollment: 200

Type: Actual

## Ethics review

Approved WMO

Application type: First submission

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

CCMO

### ID

NL26444.018.09