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...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Hearing disorders
Study type	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 traige

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 referal

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 proofs 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

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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	ID
CCMO	NL26444.018.09