IS RECALIBRATED LOUDNESS PERCEPTION BASED ON BRAINSTEM ADAPTATION?

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We would like to reproduce results found in earlier studies en supplement them with ABR (BERA) testing. This is the primary goal of the research. For measuring auditory brainstem functions, ABR is the golden standard.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON41155

Source
ToetsingOnline

Brief title
Brainstem adaption

Condition

- Other condition

Synonym
n.v.t.

Health condition

Het onderzoek heeft betrekking op normaal gehoor

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen
Source(s) of monetary or material Support: Meisnerfonds

Intervention

Keyword: brainstem adaption sound perception

Outcome measures

Primary outcome

brainstem evoked potentials

Secondary outcome

loudness scaling, stapedius reflex thresholds

Study description

Background summary

Auditory neural mechanisms in the brainstem are susceptible to change bij changing the sound input to the ear. (Formby et al. 2003, 2007). This so called neural gain is object of interest in this study. The mentioned change leads to an altered loudness perception.

Study objective

We would like to reproduce results found in earlier studies en supplement them with ABR (BERA) testing. This is the primary goal of the research. For measuring auditory brainstem functions, ABR is the golden standard.

Study design

Test subjects will be compared with themselves. A subject will be asked to wear earplugs for two weeks. Prior to this subjective and objective audiometry shall be performed, including a loudness scaling. After wearing earplugs for two weaks, the same tests shall be performed. Finally, after two more weeks (without wearing earplugs) the test shall be repeated.

Intervention

wearing earplugs

Study burden and risks

The risks involved are transient if the occur. There will be three test sessions, each 1,5 hours long. Earplugs will be made with a duration of 1 hour. The test subjects do not have an advantage or disadvantage.

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

Age >= 18 years
Normal hearing: thresholds up till 8 kHz 20 dB or less

Normal loudness tolerance
Normal middle ear function
Normal health
Geschreven informed consent

Exclusion criteria

• Otological history
• Tinnitus
• Hyperacusis
• Otological conditions prohibiting occlusion of the ear canal
• Hearing Loss
• Unobtainable ART, e.g. due to a flat tympanogram

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	24-02-2015
Enrollment:	15
Type:	Actual

Ethics review

Approved WMO

Date:	06-01-2015

Application type:	First submission
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	NL49936.042.14