The Acoustic Change Complex in normal hearing adults and adults with sensorineural hearing loss

Published: 24-04-2012
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Primary objective: To assess the level of agreement between the following tests:- The minimal frequency difference necessary to evoke an ACC in normal hearing adults and adults with SNHL (ACC threshold).- The just noticeable frequency differences...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Hearing disorders
Study type	Observational non invasive

Summary

ID

NL-OMON45183

Source
ToetsingOnline

Brief title
ACC in NH and SNHL adults

Condition

- Hearing disorders

Synonym
Deafness, Hearing Loss

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: ACC, Acoustic Change Complex, Evoked potential

Outcome measures

Primary outcome

The presence of the ACC waveform evoked by the smallest frequency change and

the just noticeable frequency difference perceived by normal hearing adults and

SNHL patients, expressed in Hz.

Secondary outcome

The speech reception in noise threshold obtained by normal hearing adults and

SNHL patients, expressed in dB.

Study description

Background summary

Our ability to understand spoken language, which is a complex sound consisting of various frequency and amplitude changes, is related to the ability to perceive subtle changes in frequencies and intensities of simple sounds as tones. Patients with sensorineural hearing loss (SNHL) experience frequently difficulties when they are asked to report small frequency and intensity changes. An electrophysiology measurement, such as the acoustic change complex (ACC), recorded from the auditory cortex, might be an appropriate objective tool, to test whether tone changes are perceived. To date, little is known about the relation of the perception of small tone changes by normal hearing subjects and subjects with SNHL and the presence of the ACC.
In this study we aim to assess the level of agreement between the ACC and small frequency changes, the so called *just noticeable differences (JND)*, perceived by normal hearing and hearing impaired adults with sensorineural hearing loss. Subjects will not have a direct benefit of this study, but the results of this study will contribute to the scientific knowledge of how frequency changes in stimuli are perceived in the auditory cortex. Furthermore, a high level of agreement between the ACC and the JND might lead to the development of a new objective test to evaluate the frequency discrimination in patients who are unable to reliably report these subtle differences, such as children. The ACC might also be useful in the follow-up of cochlear implant patients.

Musical training improves frequency JNDs and speech in noise perception. Because of the therapeutic potential of musical training we like to examine, as secondary objective, the effect of musical training on ACCs and frequency JNDs.

Study objective

Primary objective:
To assess the level of agreement between the following tests:
- The minimal frequency difference necessary to evoke an ACC in normal hearing adults and adults with SNHL (ACC threshold).
- The just noticeable frequency differences perceived by normal hearing adults and adults with SNHL (JND threshold).

Secondary objectives:
To assess the relation between the speech reception in noise threshold and the ACC and JND thresholds.
To assess the effect of hearing loss and musical training on ACCs and JNDs
To evaluate the repeatability of the ACC recordings in normal hearing adults and adults with SNHL within one test session.

Study design

24 normal hearing subjects and 24 subjects with sensorineural hearing loss will be included in this observational study. All participants will be subject to three tests: ACC recordings, JND tests and speech-in-noise test. A standard audiogram will be measured to assess the hearing (normal or loss). A music questionnaire will be completed by the subject to assess the musical training.

Study burden and risks

The ACC recording, the just noticeable difference tests and the speech reception in noise tests are considered as a non-risk investigation; adverse events are not expected to occur during the measurements. The expected burden due to participation for all participants consists of one session of approximately 3,5 hours.
Subjects will not have a direct benefit of this study, but the results of this study will contribute to the scientific knowledge of how frequency changes in stimuli are perceived in the auditory cortex. Furthermore, a high level of agreement between the ACC and the JND might lead to the development of a new objective test to evaluate the frequency discrimination in patients who are unable to reliably report these subtle differences, such as children. A confirmation of benefit of musical training for ACC and JND might lead to hearing therapy based on music.

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

Normal hearing group:
- Age >=18 years
- Written informed consent
- Hearing thresholds standard audiometric test (125 - 8000Hz) <= 20 dB HL and an average over 500-1000-2000-4000 Hz <= 15 dB HL ;SNHL group:
- Age >=18 years
- Written informed consent
- Hearing thresholds standard audiometric test (125 - 8000Hz) > 20 dB HL and an average over 500-1000-2000-4000 Hz > 15 dB HL
- Average air-bone gap of <= 7.5 dB over 250-500-1000-2000 Hz

Exclusion criteria

- Neurological or mental disorders
- Use of anticonvulsant medication or psychotherapeutic drugs

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:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	28-06-2012
Enrollment:	48
Type:	Actual

Medical products/devices used

Generic name:	ACC/CEAP stimulation with DECOS patientinterface PI2496-R
Registration:	No

Ethics review

Approved WMO

Date:	24-04-2012
Application type:	First submission
Review commission:	METC NedMec

Approved WMO

Date:	17-10-2012
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	14-04-2015
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	14-02-2018
Application type:	Amendment
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	NL37719.041.11

Study results

Results posted: 11-01-2023

Summary results
Trial ended prematurely

First publication
01-01-1900

URL result

Type
ext
Naam
doi.org
URL
Type
ext
Naam
doi.org
URL