Reduction of otoacoustic emission with transcranial magnetic stimulation (TMS) of the auditory cortex

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Ethical review	Approved WMO
Status	Pending
Health condition type	Inner ear and VIIIth cranial nerve disorders
Study type	Observational invasive

Summary

ID

NL-OMON32299

Source
ToetsingOnline

Brief title
Otoacoustic emission after rTMS

Condition

- Inner ear and VIIIth cranial nerve disorders

Synonym
click-evoked OAEs, sounds from the ear

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen
Source(s) of monetary or material Support: NWO,Heinsius Houboltfonds

Intervention

Keyword: auditory cortex, efferent olivocochlear pathway, otoacoustic emission, Transcranial Magnetic Stimulation

Outcome measures

Primary outcome

The amplitude of the otoacoustic emission of the ear contralateral to the side

of the stimulation.

Secondary outcome

The secondary endpoint will be the difference in amplitude reduction of the

OAEs with respect to the different frequencies compared to placebo.

Study description

Background summary

Until recently only the medial olivocochlear efferent pathway in humans could be demonstrated. But now the existence of an auditory corticofugal pathway in humans has been demonstrated with direct electrical stimulation of the auditory pathway by an implanted cortical electrode. The electrical stimulation of the auditory cortex with the implanted electrode resulted in reduction of the otoacoustic emissions (OAEs), sounds that are produced by the cochlea itself. Reduction of OAEs by stimulation of the efferent auditory pathway gives a new insight in the inhibitory qualities of the central auditory system. Potentially Transcranial Magnetic Stimulation (TMS), a form of indirect electrical stimulation of the cortex, can give this reduction in OAE as well. This can have great implications for research of the central auditory system and the therapeutic use of TMS.

Study objective

The main objective is to demonstrate the activation of the efferent inhibitory cortico-olivocochlear pathway with otoacoustic emission of the ear contralateral to the side of stimulation with TMS. We expect the amplitude to decrease after TMS of the auditory cortex. The secondary objective is to determine if the reduction in amplitude of the OAEs depends on the different

frequency used for TMS stimulation.

Study design

This study is an exploratory placebo-controlled intervention study with a cross-over design.

Study burden and risks

The risk associated with TMS is a potential epileptic seizure. This risk is not to be expected with the stimulation parameters used in this study and in accordance with international safety guidelines for TMS.
Participation requires a total of 4 visits, with a total of 4 hours.

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

Participated successfully in mentioned MRI studies
Presence of click-evoked OAEs in both ears
No otologic medical history
> 18 years of age

Exclusion criteria

•Presence of any major medical, neurological or psychiatric diagnoses now or in the past, specific epilepsy, severe head injury, increased intracranial pressure or previous cranial neurosurgery
•Metal parts inside the subject*s head (except in the mouth) or elsewhere in the body
•Cardiac pacemaker and/or implanted medication pump and/or intercardiac lines
•Use of drugs or medications that reduce cortical excitation such as anticonvulsants, benzodiazepines or other sedatives (e.g. antihistamines)
•Use of drugs or medications that reduces the seizure threshold, such as tricyclic anti-depressants and antipsychotic drugs.
•Pregnancy

Study design

Design

Study type:	Observational invasive
Intervention model:	Crossover
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Placebo
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-04-2008
Enrollment:	15
Type:	Anticipated

Ethics review

Approved WMO
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	NL21863.042.08