Functional Connectivity in the Central Auditory System; Optimization of the Acoustic Environment

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Ethical review	Approved WMO
Status	Recruiting
Health condition type	Other condition
Study type	Observational non invasive

Summary

ID

NL-OMON29877

Source
ToetsingOnline

Brief title
Optimization of Auditory Connectivity Measurements

Condition

- Other condition

Synonym
N.a. (this proposal does not study any disorder)

Health condition

Gehooraandoeningen

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Central auditory system, Functional connectivity, Functional MRI (fMRI), Scanner noise

Outcome measures

Primary outcome

Activation and connectivity levels in various brain areas that are involved in

auditory processing during sparse and continuous paradigms with/without sound

presentation, as well as statistical descriptors of the underlying fMRI signals.

Due to the exploratory character of this study, the variables and parameters of

interest will not be specified further beforehand.

Secondary outcome

N.a.

Study description

Background summary

In the last decade is has become possible to study the functioning of the central auditory system in the human brain by means of functional MRI (fMRI). Using this method, the brain activity that occurs in response to a presented stimulus can be mapped. However, conventional stimulus-related fMRI experiments are hardly applicable in some cases, for example when the subject's sound perception cannot be controlled properly. This is for instance the case in tinnitus patients that perceive unremitting sounds in the absence of any external sound sources ('ringing in the ears').
Recently, methodologic studies have appeared describing new fMRI methods that are not aimed at determining activation in brain areas, but that focus on connectivity between brain areas. Due to this difference, such methods depend less upon well-defined stimulus conditions, which may make them very

appropriate to study the aforementioned tinnitus patients.
When investigating the central auditory system using fMRI, specific problems arise because of the presence of scanner noise. During measurements, MR-scanners produce very intense acoustic noise, which is perceived by the subject and thus interferes with the neural activity in the auditory brain areas. For conventional fMRI-setups, practical measures exist to minimize the influence of this noise. However, it is yet unknown whether these measures are equally suitable in the context of new connectivity related fMRI methods.

Study objective

The objective of this study is to determine the influence of ambient noises upon the characteristics of fMRI signals that are of relevance in connectivity measurements.
The study will focus on the influence on the statistical properties of measurable fMRI signals of scanner noise in particular. Additionally, the effectiveness of so-called sparse acquisition paradigms will be compared to that of continuous paradigms (sparse paradigms are common in conventional fMRI setups to limit the influence of scanner noise). Finally, it will be studied whether it is advantageous to excite the central auditory system by means of sound presentations on behalf of determining connectivity parameters.

Study design

After inclusion, the subject will undergo a clinical hearing test to verify that their hearing is normal. Hereafter, subject will participate in an fMRI session. Apart from a number of orienting anatomical scans, this will consist of series of functional acquisitions that are capable of detecting brain activation and connectivity. These series will comprise blocks of sparse and continuous acquisitions, that will be randomly alternated. In addition, sound fragments will be presented during some blocks, while no sound will be audible in other blocks (except for the scanner noise). The subjects are instructed to memorize the sound fragments during the blocks with sound presentation. In a task that is performed immediately after the fMRI session, a series of sound fragments will be presented in which the subject is asked to indicate whether these are familiar from the previous fMRI session or not.
To assess the reproducibility of the measurements, half of the subjects will be requested to participate in an identical fMRI session on a later day.

Study burden and risks

The burden will consist of participation in a hearing test of approx. 10 minutes, followed by an fMRI session and sound recognition task of 2 hours (taken together). Half the subjects will participate a second time in an identical fMRI session and sound recognition task.

Risks are naught.

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

Adult
Healthy
Normal hearing
No contra-indications for MR
Signed informed consent

Exclusion criteria

Medical, neurological or psychiatric diagnoses
Impaired hearing
Emergence of contra-indication for MR
Claustrophobia
Epilepsy
Pregnancy
Withdrawal of willingness to participate

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	05-12-2006
Enrollment:	12
Type:	Actual

Ethics review

Approved WMO

Date:	06-09-2006
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	NL13392.042.06