Functional MR Studies of vestibular and visual interaction

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

Summary

ID

NL-OMON30086

Source
ToetsingOnline

Brief title
Vestibular fMRI

Condition

- Other condition

Synonym
nvt

Health condition

Human Neurophysiology

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Brain, fMRI, Vestibular

Outcome measures

Primary outcome

The aim of this project is to develop protocols for fMRI to demonstrate the

vestibular cortical activation in healthy volunteers, and to investigate the

brain areas that are involved in visual-vestibular interaction.

Secondary outcome

NA

Study description

Background summary

Interaction between the vestibular and visual systems can be simulated by providing caloric vestibular stimulation. When the subject*s eyes are closed, this induces a strong sense of rotation. But when the subject*s eyes are open, a mismatch is created between the vestibular system (sense of rotation) and the visual system (sense of stability). When cold water is used to provide the stimulation, slow phase eye movements (i.e., nystagmus) are resulted towards the side on which the stimulus is given and hence induced a perception of rotation rotating away (around the vertical body axis) from that side. However, when warm water is used, the slow phase eye movements are moving away from the side on which the stimulus is given and hence induced a perception of rotation rotating (around the vertical body axis) from that side .

Current approaches to study human brain activation of vestibular stimulation use of blood-flow measurement with Single Photon Emission Computed Tomography (SPECT), functional Magnetic Resonance Imaging (fMRI) and Positron Emission Tomography (PET). These imaging studies of caloric vestibular response in humans have combined unilateral stimulation or bilateral stimulation with the

combination of gas, cold water or hot water as the stimulant. These studies have always been done with the subjects* eyes closed. Up to now, however, a few comparisons have been made between unilateral and bilateral stimulations and between eyes-closed and eyes-open conditions.

Study objective

In this study we used fMRI to measure the blood oxygenated level dependent (BOLD) response during caloric vestibular stimulation. We setout to investigate the involvement of the cortical and sub-cortical brain areas during visual-vestibular interaction and compare the difference between the eyes closed and eyes open conditions with unilateral or bilateral stimulation with cold and warm water.

Primary Objective: To investigate the involvement of the cortical and sub-cortical brain areas during visual-vestibular interaction and

Secondary Objective: To compare the difference between the eyes closed and eyes open conditions with unilateral or bilateral stimulation with cold and warm water.

Study design

A volunter will be scanned twice for one hour. During the scansession cold or warm water will be injected in one or both ears.

Study burden and risks

In this study we used fMRI to measure the blood oxygenated level dependent (BOLD) response during caloric vestibular stimulation. fMRI is a non-invasive imaging technique. Brain activity in fMRI is based on the observation that increased neural activity leads to an increase in localized cerebral blood flow, blood volume, and blood oxygenation.

Each fMRI study and for each volunteer has 2 experiments and will last for 1 hour each.
During the experiment warm or cold water will be injected into the ear of the volunteer and this would induce a sensation of rotation to the volunteer. The sensation will only last for a minute or two.

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

Non

Exclusion criteria

MR contra-indications (claustrophobia) , use of medicaments, pregnancy, defect tympanic membrane

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):	18-09-2006
Enrollment:	75
Type:	Actual

Ethics review

Approved WMO

Date:	30-08-2006
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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	NL11844.078.06