The use of Functional transcranial Doppler ultrasound and repetitive Transcranial Magnetic Stimulation for the assessment of language lateralization. A comparison with functional MRI

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1) To compare fTCD with fMRI, in order to reproduce the previously shown high correlate between the two techniques. 2) to compare rTMS with fMRI and subsequently with fTCD.

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

Summary

ID

NL-OMON30061

Source
ToetsingOnline

Brief title
fMRI-fTCD-rTMS validation

Condition

- Neurological disorders NEC
- Psychiatric disorders NEC

Synonym
cerebral dominance., decreased language lateralization

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: functional magnetic resonance imaging, functional transcranial doppler ultrasound, language, transcranial magnetic stimulation

Outcome measures

Primary outcome

1) The strength of the correlation between lateralization indices, as assessed

by fMRI and fTCD. 2) The concordance in side of language lateralization as

assessed by rTMS, fMRI and fTCD.

Secondary outcome

not applicable

Study description

Background summary

Functional Magnetic Resonance Imaging (fMRI), is the current standard for non-invasive language lateralization determination. However, the use of fMRI has some restrictions. It is an outstanding technique for individual investigations or small subjects groups, but does not lend itself easily for detection of language lateralization in larger groups of subjects. Recently, functional Transcranial Doppler Ultrasound (fTCD) has been shown an alternative to non-invasively detecting cerebral language lateralization. The technique has no known side-effects or contra-indications, although it cannot be used in approximately 5% of subjects for lack of a temporal bone window. Another technique that allows for non-invasive determination of language lateralization is repetitive Transcranial Magnetic Stimulation (rTMS). RTMS can be applied for determination of language dominance, because it can induce a temporary speech arrest when applied over the dominant hemisphere. Both methods have been shown to correlate highly with fMRI measurements of language lateralizationof language lateralization.

Study objective

1) To compare fTCD with fMRI, in order to reproduce the previously shown high correlate between the two techniques. 2) to compare rTMS with fMRI and subsequently with fTCD.

Study design

Subjects participate in 5 steps: 1) fill out a 20-item questionnaire on handedness (Edinburgh Handedness Inventory, EHI). 2) Functional derivates of language lateralization will be measured using a word production test and a modified test of remote association or semantic distance. Both tests measure right hemisphere function and will be presented on a laptop. 3) Determination of language lateralization with fMRI. A functional scan of cerebral activation is obtained while subjects are engaged in a language task, wherein they silently generate words beginning with a prompted letter (paced letter fluency). The task will be projected on a screen. 4) Determination of language lateralization by fTCD. This device measures changes in flow velocity in the right and left medial cerebral arteries. Subjects will perform the same language task, which causes language areas of the dominant hemisphere to be activated to a higher degree than the contralateral areas 5) determination of language lateralization by repetitive Transcranial Magnetic Stimulation. A type of task differing from the previous experiments will be used. Subjects will speak out (e.g. counting up and down). During recitation speech will be disturbed by influencing cortical activity by inducting a low current by means of the pulsating magnetic field. Lateralization will be measured as a function of speech disruption during magnetic stimulation of left or right hemisphere motor language areas.

Study burden and risks

FTCD is a non-invasive Doppler technique that has been used extensively and has no known associated risks. People wear a headset to which the Doppler-probes are attached. When this causes distress it can easily be adjusted or taken of. MRI has been used as a diagnostic, clinical tool for over 20 years. There are no associated risks. In previous studies performed at the UMCU, all subjects tolerated a similar MRI procedure well. When subjects become anxious in the restricted space, anxiety vanishes after leaving the scanner. The main concern when using rTMS is its potential to induce a seizure. World-wide, this has occurred in only 6 healthy subjects. This has not been reported anymore since implementation of safety guidelines by Wassermann (1998). Other potential adverse effects of rTMS include induction of a muscle tension headache or a neck ache in. These are generally mild discomforts that respond promptly to a common analgesic.

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

General inclusion criteria:
1. Age between 18 and 65
2. native speaker

Exclusion criteria

specific fMRI and rTMS inclusion criteria
1. metal objects in or around the body that cannot be taken off (surgical clips, braces, pacemakers, piercings or others).
2. history of epilepsy or first degree relatives with epilepsy
3. current pregnancy.

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	13-07-2006
Enrollment:	50
Type:	Actual

Ethics review

Approved WMO

Date:	27-06-2006
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

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	NL11566.041.06