MEG language and memory mapping: a comparison with WADA

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Ethical review	Approved WMO
Status	Recruiting
Health condition type	Seizures (incl subtypes)
Study type	Observational non invasive

Summary

ID

NL-OMON35385

Source ToetsingOnline

Brief title MEG-WADA

Condition

- Seizures (incl subtypes)
- Nervous system, skull and spine therapeutic procedures

Synonym brain disease, epilepsy

Research involving

Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum Source(s) of monetary or material Support: intern

Intervention

Keyword: lateralisation, magnetoencephalography, non-invasive, verb generation and memory

Outcome measures

Primary outcome

Primary outcome is the establishment of a robust stimulation and analysis

protocol in a multi-centre study which may ultimately lead to a non-invasive

alternative to the Wada procedure for pre-surgical assessment of language and

memory function.

Secondary outcome

N/A

Study description

Background summary

To reduce the risk of aphasia or amnesia following surgical resection in patients suffering from epilepsy and/or brain tumours it is necessary to identify language and memory presentation pre-surgically. Of importance here is to determine whether there is a dominant hemisphere with regards to language and memory function. Currently, the gold standard for the evaluation of lateralised language and memory mapping is the Wada procedure. Recent advances in neuroimaging techniques however might provide us with opportunities to replace this invasive procedure with a non-invasive and cost-effective alternative to conduct pre-surgical assessment of language and memory function, and in addition, help in the planning of grid implantations.

Study objective

Our overall aim is to create a cost effective non-invasive method of pre-surgical assessment of language and memory function using MEG scanning. We propose a research project with the key objective to evaluate the effectiveness of a Dutch implementation of a language/memory stimuli and analysis protocol.

Study design

A MEG study using a silent verb generation and memory protocol.

Study burden and risks

Patients will undergo a completely non-invasive MEG recording, which will require them to lie for approximately 30 minutes in a magnetically shielded room, during which responses during a language and memory task, as well as spontaneous activity, will be recorded. The MEG sensors do not touch the head, but three separate coils are attached to the head to quantify head movement. This procedure is not painful in any way, is not considered to be difficult or stressing, and has negligible risks. In addition, besides the proposed study, a routine clinical MEG and MRI protocol will be carried out, and, as part of the pre-surgical evaluation, a Wada test.

Contacts

Public

Vrije Universiteit Medisch Centrum

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Adults (18-64 years) Elderly (65 years and older)

Inclusion criteria

Age between 18 and 85 Has had, or will undergo, a Wada test Will undergo a MEG and MRI scan as part of a pre-surgical evaluation Written informed consent Amendement: healthy volunteers for pilot study to test nre methodology

Exclusion criteria

Unable to undergo an MRI scan Insufficient mastery of the Dutch language Inability to communicate adequately

Study design

Design

Study type: Observational non invasive		
Masking:	Open (masking not used)	
Control:	Uncontrolled	
Primary purpose:	Diagnostic	

Recruitment

NL	
Recruitment status:	Recruiting
Start date (anticipated):	21-07-2009
Enrollment:	10
Туре:	Actual

Ethics review

Approved WMO

Date:	16-06-2009
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	01-12-2010
Application type:	Amendment
Review commission:	METC Amsterdam UMC

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 CCMO

ID NL26907.029.09