

Silent Period induced by Transcranial Magnetic Stimulation in healthy volunteers, reference values and interobserver variability for the triceps brachii and forearm extensor muscles.

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The main objective of the study is: what are normal values for TMS parameters of arm extensor muscles in healthy human subjects? Secondary objectives are: (1) which forearm extensor muscle is most appropriate for a TMS study and (2) what is the...

Ethical review	Approved WMO
Status	Pending
Health condition type	Central nervous system vascular disorders
Study type	Observational non invasive

Summary

ID

NL-OMON32314

Source

ToetsingOnline

Brief title

TMS-SPRITE

Condition

- Central nervous system vascular disorders

Synonym

cerebrovascular accident, stroke

Research involving

Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Sint Radboud

Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: interobserver variability, reference values, transcranial magnetic stimulation, upper extremity

Outcome measures

Primary outcome

The main study parameters are the determinants of the S-R curves of MEP AUC and SP, which are slope, plateau value and X-intercept of the tangent.

Secondary outcome

The secondary study parameters comprise the outcomes of a questionnaire (visual analog scale - VAS) concerning experienced pain and discomfort of the TMS procedures.

Study description

Background summary

Rationale: This study is an extension of the study of A.A. van Kuijk on the predictive value after a cerebro-vascular accident (CVA) of motor evoked potentials (MEPs) and silent periods (SPs) as evoked in arm muscles with transcranial magnetic stimulation (TMS). The value of extension of the upper extremity as a predictive measure for long-term functional recovery after a CVA has been established, but corresponding TMS parameters of arm extensor muscles remain to be explored. Since studying these muscles with TMS represents a novel approach, first reference values in healthy controls and interobserver validity of the measurements need to be substantiated.

Study objective

The main objective of the study is: what are normal values for TMS parameters of arm extensor muscles in healthy human subjects? Secondary objectives are:

(1) which forearm extensor muscle is most appropriate for a TMS study and (2) what is the interobserver variability of a TMS study of the arm extensors?

Study design

Cross-sectional study

Study burden and risks

Theoretically, people undergoing TMS could develop an epileptic insult. However, few incidents have been described. No other risks are known. It is expected that TMS of arm extensors can significantly contribute to knowledge and therapy aims in CVA patients, and the risks are considered minimal in comparison to the benefits of the study.

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

age over 18 years

capable of understanding written and verbal information

capable of following verbal instructions

Exclusion criteria

history of neurological damage or disease

recent history of injury or disease involving an upper extremity

history of psychiatric disease

history of seizures or epilepsy

pacemaker or other metal implants in the upper body

pregnancy

Study design

Design

Study type: Observational non invasive

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Other

Recruitment

NL

Recruitment status: Pending

Start date (anticipated): 01-09-2008

Enrollment: 30

Type: Anticipated

Ethics review

Approved WMO

Date:	23-10-2008
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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	NL22925.091.08