The CMAP scan: Collecting normal values in a healthy population

Published: 25-06-2008
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Primary Objective: Collection of CMAP scan normal valuesSecondary Objectives: Assessment of the influence of gender, age, and side on the CMAP scan and its variables

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

Summary

ID

NL-OMON31884

Source
ToetsingOnline

Brief title
CMAP scan normal values

Condition

- Neuromuscular disorders

Synonym
-

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: Compound muscle action potential, Normal values, Scan, Stimulus-response curve

Outcome measures

Primary outcome

This study will collect normal values for the CMAP scan variables threshold

intensity S0, maximum intensity S100, maximum CMAP, asymmetry, number of steps,

step size, and summed step size as percentage of the maximum CMAP.

Secondary outcome

-

Study description

Background summary

The CMAP scan is a noninvasive neurophysiological tool that records the electrical activity of a muscle in response to repetitive transcutaneous stimulation of the motor nerve. Patterns in or properties of this CMAP scan provide clinically relevant information and the method is easy to apply and interpret. For these reasons, the scan is a promising new diagnostic instrument. A further description of the method can be found in the protocols of previously approved studies MEC-2005-277 and MEC-2007-205. The former study concerned the initial exploration of the approach and has led to a peer-reviewed publication in 2007.1 The second study addressed the optimal settings for performing a CMAP scan. A publication of this study is in preparation, and its results will be applied in the present study.

The next step toward establishing the CMAP scan as a novel electrodiagnostic instrument is the determination of the distribution of CMAP scan variables that is present in a healthy population. This is an essential step in the validation of the method, because to be able to qualify a scan as abnormal, limits to what is normal need be known. Since normal values may be age-, gender-, side- and muscle-dependent, normal values will be collected for each of these subcategories.

Study objective

Primary Objective:
Collection of CMAP scan normal values

Secondary Objectives:
Assessment of the influence of gender, age, and side on the CMAP scan and its variables

Study design

In this cross-sectional observational multicenter study, we will record CMAP scans bilaterally in 6 different muscles of 140 healthy subjects: 10 male and 10 female, in each of the categories 18-29, 30-49, 40-49, 50-59, 60-69, 70-79, and >= 80 years of age.

The CMAP scan was initially designed in the Erasmus MC and continues to be developed with three international centers: Mayo Clinics, Rochester, USA; University of Utah, Salt Lake City, USA; and Royal Women*s and Children*s Hospital, Brisbane, Australia. Each of these centers has agreed to study at least 20 healthy subjects.

Study burden and risks

The investigations are noninvasive. There are no risks, nor are there immediate benefits for individual subjects.

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 >18
normal nerve conduction study of the median nerve
written informed consent

Exclusion criteria

neurological disease
Any psychological, familial, sociological and geographical condition potentially hampering compliance with the study protocol. Judgment is up to the investigator.

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):	01-07-2008
Enrollment:	80
Type:	Actual

Ethics review

Approved WMO Date:	25-06-2008
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	NL22976.078.08