

# The excitability of peripheral nerves following acute stroke: A 6-month follow-up study using neurophysiological and clinical tests

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- To confirm findings in previous studies regarding the loss of functioning motor units in the first day after acute stroke. - To study peripheral nervous system excitability in order to be able to formulate a more detailed hypothesis regarding the...

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Recruiting
<b>Health condition type</b>	Central nervous system vascular disorders
<b>Study type</b>	Observational non invasive

## Summary

### ID

NL-OMON34667

### Source

ToetsingOnline

### Brief title

EXIST

### Condition

- Central nervous system vascular disorders

### Synonym

cerebrovascular accident, stroke

### 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:** Excitability, Motor unit number estimation, Peripheral nervous system, Stroke

## Outcome measures

### Primary outcome

For neurophysiology: estimates of the number of functioning motor units (MUNEs) and excitability variables obtained with threshold tracking techniques. For clinical stroke assessment: questionnaires (NIHSS) and scales (modified Rankin scale, Barthel index), CT, the TOAST classification of stroke subtype, and an evaluation of cardiovascular risk factors.

### Secondary outcome

N.v.t.

## Study description

### Background summary

Stroke often results in loss of motor function. An obvious explanation for this loss is that the muscles that were under the control of the lesioned part of the central nervous system can no longer be activated voluntarily. However, several recent studies suggest that external stimulation of the peripheral nervous system also elicits a diminished response from affected muscles. These changes appear to occur within 24 hours following the stroke. This surprising finding suggests that the function of the peripheral nervous system itself becomes impaired, primarily with respect to its (in)ability to conduct electrical signals.

### Study objective

- To confirm findings in previous studies regarding the loss of functioning motor units in the first day after acute stroke.
- To study peripheral nervous system excitability in order to be able to formulate a more detailed hypothesis regarding the causes of this loss (if

present)

- To assess whether the onset and progression of electrophysiological abnormalities are related to functional outcome and may, hence, potentially be used as prognostic factors.

## **Study design**

In this prospective study, patients with acute ischemic stroke will be evaluated with neurophysiological and clinical tests. Measurements will be performed six times between stroke onset (within 24 hours) and six months later.

## **Study burden and risks**

The investigations are non-invasive. There are no risks. The patients do not gain any direct benefit from the study.

## **Contacts**

### **Public**

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### **Scientific**

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## **Trial sites**

### **Listed location countries**

Netherlands

## **Eligibility criteria**

## Age

Adults (18-64 years)

Elderly (65 years and older)

## Inclusion criteria

- A first-ever ischemic stroke
- Hemiplegia, including weakness of the hand muscles
- Stroke onset < 24 hours before the first recordings
- Stable vital signs

## Exclusion criteria

- Non stroke-related sensory or motor impairments
- Any peripheral lesion of the median nerve, such as nerve root compression syndrome, cervical spondylosis, carpal tunnel syndrome, or other peripheral neuropathy revealed by neurological examinations and electrodiagnostic tests
- Any history of other diseases or treatment that might have affected the peripheral nerve

## Study design

### Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)

**Primary purpose:** Basic science

### Recruitment

NL	
Recruitment status:	Recruiting
Start date (anticipated):	02-02-2010
Enrollment:	116
Type:	Actual

## Ethics review

Approved WMO

Date: 15-01-2010

Application type: First submission

Review commission: METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

Approved WMO

Date: 29-06-2010

Application type: Amendment

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	NL30323.078.09