The relation between somatosensation, nociception and the development of shoulder pain after stroke.

Published: 29-04-2009
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To identify somatosensory and nociceptive changes in the acute phase after stroke in relation to the development of shoulder pain.

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

Summary

ID

NL-OMON33220

Source
ToetsingOnline

Brief title
The development of shoulder pain after stroke

Condition

- Central nervous system vascular disorders

Synonym
cerebro vacular accident, Stroke

Research involving
Human

Sponsors and support

Primary sponsor: Universiteit Twente
Source(s) of monetary or material Support: Universiteit Twente & het Roessingh

Intervention

Keyword: nociception, shoulder pain, somatosensation, stroke

Outcome measures

Primary outcome

Baseline assessment consists of the assessment of pain complaints (current, past) and assessment of neurological function. Follow-up measurements consist of the assessment of pain complaints (quality, quantity) and the assessment of somatosensory and nociceptive changes using quantitative sensory testing and cold pressor testing.

Secondary outcome

x

Study description

Background summary

Shoulder pain is a common complication after stroke and in some cases difficult to treat. Better prevention in the acute stroke phase and appropriate treatment in of shoulder pain may be accomplished when more is known about the neurophysiological mechanisms underlying the development and chronification of shoulder pain after stroke.

Study objective

To identify somatosensory and nociceptive changes in the acute phase after stroke in relation to the development of shoulder pain.

Study design

Prospective study. Patients are assessed from the acute phase (within 2 weeks) after stroke up to 6 months post-stroke. Follow-up takes place at 3 and 6 months post-stroke.

Study burden and risks

The burden and risks of participation are low. Previous research in the acute phase after stroke shows that baseline assessment of 45 minutes at the hospital bed-side does not impose much burden upon the patient. Follow-up measurements maximally take 1.5 hour per follow-up. All methods are non-invasive. The burden of participation is low. There are no physical and mental risks of participation. Participation does not interfere with treatment.

Contacts

Public
Universiteit Twente

Postbus 217
7500 AE
Nederland
Scientific
Universiteit Twente

Postbus 217
7500 AE
Nederland

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Older than 18 years, legally competent, able to communicate, first-ever unilateral CVA

(ischemic or hemorrhagic) of the middle cerebral artery (if possible confirmation by CT or MRI scan), somatosensory and motor loss during baseline measurement (0-2 weeks after stroke), sign informed consent

Exclusion criteria

Pregnancy, HIV/AIDS, any other brain disease (trauma, tumor, parkinson, multiple sclerosis), any peripheral neurological disease (amputation, neuropathy), pre-existent psychiatric disorders, pre-existent use of psychotropic substances or medication, chronic pain complaint (> 3 subsequent months) in the 6 months prior to stroke

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):	19-05-2009
Enrollment:	100
Type:	Actual

Ethics review

Approved WMO

Date:	29-04-2009
Application type:	First submission
Review commission:	METC Twente (Enschede)

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	NL26665.044.09
Other	voorlopig nummer: TCNR = 5556