# Positioning and electrical stimulation in stroke.

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| **Ethical review** | Approved WMO |
| **Status** | Recruitment stopped |
| **Health condition type** | Connective tissue disorders (excl congenital) |
| **Study type** | Interventional |

## Summary

### ID

NL-OMON32161

**Source**
ToetsingOnline

**Brief title**
PAESIS-trial

### Condition

- Connective tissue disorders (excl congenital)
- Central nervous system vascular disorders

**Synonym**
cerebrovascular accident (CVA), stroke

**Research involving**
Human

### Sponsors and support

**Primary sponsor:** Universitair Medisch Centrum Groningen
**Source(s) of monetary or material Support:** Fonds Nuts Ohra

## Intervention

**Keyword:** preventive therapy, randomized controlled trial, stroke, upper extremity

## Outcome measures

### Primary outcome

1. Passive range of motion of the shoulder, elbow, forearm and wrist using a masked fluid-filled goniometer.

2. Shoulder pain using a Dutch translation of the AbilityQ/ShoulderQ. This is a questionnaire.

### Secondary outcome

1. Impact of arm spasticity on arm activities in daily life using the Leeds Arm Spasticity Impact Scale (LASIS). This is a questionnaire.

2. Spasticity/hypertonia of the shoulder internal rotators, elbow flexors and extensors and the long finger flexors using the Modified Tardieu Scale.

3. The amount of use of spasticity and pain medication.

4. Selective movement ability of the hemiplegic arm using the 66-point arm section of the Fugl-Meyer Assessment.

5. The degree of shoulder subluxation using a simple clinical scale.

# Study description

### Background summary

Each year more than 41.000 people are struck by a stroke in the Netherlands. In more than 60% of the cases the hemiplegic arm remains without function. Disuse of the arm makes it prone to the occurrence of contracture formation and spasticity. This results in hemiplegic shoulder pain, motor impairments and activity limitations (e.g. cleaning the arm, dressing). Available evidence based single-modality treatments are not suitable for patients with poor motor

performance, and severely affected patients are underrepresented in the research literature. Positioning procedures and electrical stimulation both seem best suitable for severely affected stroke patients and combining these treatment modalities may even be more efficacious. We hypothesize that the electrical stimulation intensifies the effect of the positioning procedure, resulting in (slowing down) contracture formation, less hemiplegic shoulder pain, less restrictions in the stroke patient*s performance of arm activities in daily life, decreased levels of spasticity and prevention of subluxation.

## Study objective

The objective of the study is to assess whether 1) two of the questionnaires used are appropriate for this subgroup of stroke patients and 2) the combination of positioning of the hemiplegic arm with simultaneous application of electrical stimulation affects the post/subacute stroke patient's arm joint range of motion/degree of contracture, the occurrence of shoulder pain, restrictions in performance of arm activities in daily life, the degree of spasticity, the amount of intake of spasticity- and pain reducing medication, the ability to make selective arm movements and the degree of shoulder subluxation.

## Study design

A multicenter single-blind (observer blind) randomized controlled trial.

## Intervention

In addition to the care as usual, subjects allocated to the experimental group will undergo 8 weeks of shoulder/arm positioning combined with therapeutic electrical stimulation of the extensor muscles of the forearm and external rotator muscles of the shoulder according to a well-defined (positioning) procedure. The positioning procedure will be prescribed for 2 times a day for 45 minutes on working days (5 days a week), totalling up to 7.5 hours a week and 60 hours during the 8 weeks of participation. During the 8 weeks of participation, electrical stimulation time will gradually be increased from 2 times 10 minutes a day to 2 times 45 minutes a day after 2 weeks onto the end of the treatment period. In addition to the usual care, subjects allocated to the control group will the same frequency/intensity of shoulder/arm positioning at about 50% of their maximum range of shoulder abduction. In this position, the extensors of the forearm will be given a low-intensity conventional transcutaneous electrical nerve stimulation (TENS) application.

## Study burden and risks

During this trial, all participating patients will receive care as usual as prescribed by their physiatrist. In addition the experimental and control

treatments are given, implying increased intensity of attention and/or *training* for the involved upper limb. Because a sham treatment is given to the control group we expect a difference between the two groups in favor of the experimental group. A sham treatment is necessary to be able to evaluate the effectiveness of the experimental treatment procedure. Both interventions are well tolerated, are easily added to the usual rehabilitation programme and therefore the burden of participation is minimal. The risks associated with electrical stimulation are minimal. The application of electrical stimulation can cause red coloration of the skin under the electrodes after use, but this is usually gone within the hour after cessation of the stimulation. Some people are allergic to the gel-elektrodes, but this rare reaction can be overcome by using hypo-allergenic (allergy-neutral) elektrodes. In case of overdosage, skin irritation can occur. This however is prevented by administering the electrical stimulation with a minimum of 4 hours between each treatment session and carefully checking the skin before and after each session.

# 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

1. A first ever or recurrent stroke except subarachnoid hemorrhages,
2. Age above 18,
3. Between 2 and 8 weeks post-stroke,
4. An apparent paralysis / severe paresis of the involved upper limb.

### Exclusion criteria

1. Any of the following contra indications for electrical stimulation: metal implants in the involved arm or shoulder, cardiac pacemaker, thrombosis, (thrombo)phlebitis, cancerous lesions, skin infections on forearm or shoulder blade, epileptic seizures six months previous to and/or since the stroke, pregnancy and myasthenia gravis/myotonia,
2. Pre-existent impairments of the affected arm (e.g. peripheral neuropathy, frozen shoulder),
3. The ability to make selective movements of the hemiplegic arm (more than 18 points on the shoulder-and elbow sections of the Fugl-Meyer Assessment arm score),
4. Severe cognitive deficits and/or severe language comprehension difficulties (more than one of four questions wrong on the verbal items of the AbilityQ),
5. Severe neglect (a difference of more than three on the letter cancellation test),
6. Severe loss of pain sensation. This criterium is tested by administering electrical stimulation to the extensor muscles of the forearm arm of the subject. If a patient shows a good motor response during stimulation, but does not feel the stimulation, he/she is excluded if (any) skin irritation occurs after a test-session of 10 minutes using the parameters of the experimental procedure. Patients with severe loss of pain sensation who tolerate the test session well will, for extra safety purposes, receive checks after each electrical stimulation session during participation.

## Study design

### Design

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| Study phase: | 3 |
| Study type: | Interventional |
| Intervention model: | Parallel |
| Allocation: | Randomized controlled trial |
| Masking: | Single blinded (masking used) |

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| Control: | Active |
| Primary purpose: | Prevention |

### Recruitment

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| Recruitment status: | Recruitment stopped |
| Start date (anticipated): | 10-09-2008 |
| Enrollment: | 36 |
| Type: | Actual |

## Ethics review

Approved WMO

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| Application type: | First submission |
| Review commission: | METC Universitair Medisch Centrum Groningen (Groningen) |

## 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 | NL22402.042.08 |