# Single-port thoracoscopic sympathicotomy for treatment of complex regional pain syndrome type I, a feasibility study.

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The effect of the intervention on pain an regain of function in de affected extremity. This will be quantified in multiple questionnaires at baseline and three follow-up points, and by clinical evaulation of the hand function at baseline and two...

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| **Ethical review** | Approved WMO |
| **Status** | Recruitment stopped |
| **Health condition type** | Epidermal and dermal conditions |
| **Study type** | Interventional |

## Summary

### ID

NL-OMON36901

**Source**
ToetsingOnline

**Brief title**
SPTS in CRPS

### Condition

- Epidermal and dermal conditions
- Nervous system, skull and spine therapeutic procedures

**Synonym**
posttraumatic dystrophy, posttraumatic paindydrome

**Research involving**
Human

## Sponsors and support

**Primary sponsor:** Universitair Medisch Centrum Groningen
**Source(s) of monetary or material Support:** Ministerie van OC&W

## Intervention

**Keyword:** CRPS-I, single-port, sympathicotomy, VATS

## Outcome measures

### Primary outcome

Pain, measured in Visual Analoque Scale (VAS)-Score

### Secondary outcome

- Function in the extremity (RASQ-questionnaire and function tests)

- Health Related Quality of Life (SF-36 questionnaire)

# Study description

### Background summary

CRPS type-1 is a pain syndrome that usually develops after an initiating noxious event (e.g. fracture) in an extremity. Although treatment options life dimethyl-sulphoxide (DMSO), N-acetylcysteine (NAC) and intensive physical therapy exist, the treatment effect is often unsatisfactory, even leading to amputation of the extremity. Surgical treatment of chronic pain disorders by dividing the sympathetic chain is an established treatment. Its more invasive nature has prevented widespread application. After introduction of minimal invasive techniques in recent years, the UMCG has now devised a truly minimal invasive, yet safe and effective thoracoscopic technique, that requires only a single 1 cm long incision in the anterior axillary line. This technique is developed as treatment for primary focal axillary and palmar hyperhidrosis, and is performed in over 50 patients producing very satisfying results. This fact has led to the hypothesis that this same surgical technique can offer this group of chronic pain patients a safe, effective treatment modality.

### Study objective

The effect of the intervention on pain an regain of function in de affected extremity. This will be quantified in multiple questionnaires at baseline and

three follow-up points, and by clinical evaulation of the hand function at baseline and two follow-up points.

### Study design

Single center prospective feasibility study

### Intervention

Unilateral single-port VATS sympathicotomy on T2-T5 level.

### Study burden and risks

Participants will have to fill-out 2 questionnaires at baseline and at three different points of follow- up. They will undergo pre-operative clinical examination at the hand clinic of the rehabilitation center, routine blood and urine testing, ECG, and pre- and postoperative chest X-ray examination. At 1 and 6 months follow-up several parameters measuring hand function will be evaluated in a clinical setting. Risks associated with the intervention include chylothorax and pneumothorax requiring prolonged drainage (<1%), bleeding, and surgical wound infection (<1%). Compensatory hyperhidrosis (excessive sweating) and referred pain have been described (<6%) after such procedures performed as treatment for primary hyperhidrosis. It is not known if this side-effects is seen when the operation is performed for the indication CRPS-I.

## 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

CRPS-I refractory to standard treatment
Age 18-65 years

### Exclusion criteria

COPD > Gold I
>20 packyears smoking
Previous thoracic surgery on affected side

## Study design

### Design

**Study type:** Interventional

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|---|---|
| Masking: | Open (masking not used) |
| Control: | Uncontrolled |
| Primary purpose: | Treatment |

### Recruitment

NL

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|---|---|
| Recruitment status: | Recruitment stopped |
| Start date (anticipated): | 01-12-2012 |
| Enrollment: | 20 |
| Type: | Actual |

# Ethics review

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| Approved WMO Date: | 28-11-2012 |
| 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 | NL41466.042.12 |