# Single-port thoracoscopic sympathicotomy for treatment of raynaud's phenomenon, a feasibility study.

Published: 01-09-2015
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To quantify blood-flow changes after unilateral sympathicotomy

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|---|---|
| **Ethical review** | Approved WMO |
| **Status** | Recruitment stopped |
| **Health condition type** | Vascular haemorrhagic disorders |
| **Study type** | Interventional |

## Summary

### ID

NL-OMON46918

**Source**
ToetsingOnline

**Brief title**
SPTS in Raynaud's

### Condition

- Vascular haemorrhagic disorders

**Synonym**
Raynaud's disease

**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:** Raynaud, Sympathicotomy

## Outcome measures

### Primary outcome

Cooling pletysmography

Nailbed microscopy

### Secondary outcome

Quality of life

Comlaints diary

# Study description

### Background summary

Raynaud phenomenon is a disease affecting predominantly young people, leading to painful, cold and white fingers, often impairing hand and finger function. Treatments excist, including medication. However, a number of patients do not respond to all known treatments. In this group we would like to evaluate the effect of a minimal invasive sympathicotomy (intra-thoracic lesion of the sympathetic nerve). This treatment is frequently used in patients with severe hyperhidrosis of the hands and axillary region, not responding to other treatments. Since in this patients a known (side) effects is a increase in manual blood flow, it makes sense to deduct that people suffering from severe raynaud's will benefit to.

### Study objective

To quantify blood-flow changes after unilateral sympathicotomy

### Study design

Single-center feasibility study in 10 patients. Unilateral intervention en quantification of blood-flow and quality of life. When effective, treatment on the opposite side will be offered.

**Intervention**

Unilateral single-port sympathicotomy

**Study burden and risks**

The complaints in this patients group are very intense. The minimal invasive procedure might offer a elegant, permanent solution, without serious risks.

## Contacts

**Public**
Universitair Medisch Centrum Groningen

Hanzeplein 1
Groningen 9713 GZ
NL
**Scientific**
Universitair Medisch Centrum Groningen

Hanzeplein 1
Groningen 9713 GZ
NL

## Trial sites

### Listed location countries

Netherlands

## Eligibility criteria

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

### Inclusion criteria

18-65 years of age

Severe form of RP, defined as clinical need of prostacyclin analogue infusions having been given in the preceding 2 years, without satisfying result OR
Severe form of RP, defined as clinical limiting in everyday life for the patient with presence of a contra-indication for prostacyclin, without satisfying result of standard care.

### Exclusion criteria

- Due to higher risk of complications following unilateral lung-deflation and re-insufflation:
o Known COPD with evidence of emphysematous lung destruction on X-thorax or CT
o History of smoking > 20 pack years
o Lung involvement due to systemic autoimmune disease (based on previously described abnormalities on HRCT or documented pulmonary hypertension by mean pulmonary artery pressure 25 mmHg at rest measured by right heart catherisation).
- Concurrent neurological disease

## Study design

### Design

**Study type:** Interventional

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

### Recruitment

NL

| | |
|---|---|
| Recruitment status: | Recruitment stopped |
| Start date (anticipated): | 12-05-2016 |
| Enrollment: | 10 |
| Type: | Actual |

## Ethics review

Approved WMO

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|---|---|
| Date: | 01-09-2015 |
| Application type: | First submission |

| | |
|---|---|
| Review commission: | METC Universitair Medisch Centrum Groningen (Groningen) |
| Approved WMO Date: | 12-03-2018 |
| Application type: | Amendment |
| 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 |
|---|---|
| ClinicalTrials.gov | NCTvolgtnog |
| CCMO | NL52348.042.15 |