

# A randomised controlled trial to evaluate the effect of gloves containing silver fibre on burden caused by Raynaud's phenomenon in patients with systemic sclerosis

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To determine the efficacy of silver enhanced gloves in decreasing burden of Raynaud's phenomenon in patients with systemic sclerosis.

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Recruitment stopped
<b>Health condition type</b>	Autoimmune disorders
<b>Study type</b>	Interventional

## Summary

### ID

NL-OMON55595

### Source

ToetsingOnline

### Brief title

HANDS ON

### Condition

- Autoimmune disorders

### Synonym

Raynaud's phenomenon, scleroderma

### Research involving

Human

## Sponsors and support

**Primary sponsor:** Leids Universitair Medisch Centrum

**Source(s) of monetary or material Support:** Afdelingsfonds afd. Reumatologie LUMC

## Intervention

**Keyword:** Microangiopathy, Raynaud's phenomenon, Silver gloves, Systemic sclerosis

## Outcome measures

### Primary outcome

The primary endpoints of this study are the Raynaud Condition Score and the VAS for burden caused by Raynaud's.

### Secondary outcome

Secondary endpoints include frequency and duration of Raynaud's attacks and a VAS for warmth of the hands as documented by the patients in a web-based log, the degree of microangiopathy as assessed by Nailfold Capillary Microscopy (NCM), the number of incident digital ulcers (DU) and the Scleroderma Health Assessment Questionnaire (SHAQ).

## Study description

### Background summary

For over a decade, adults suffering from Raynaud's phenomenon secondary to systemic sclerosis, have been supplied with textiles (gloves, socks, shirts and pants) which contain silver fibres. In general, patients state to experience benefit from wearing these cloths. However, no substantial research has been done to provide objective evidence supporting the hypothesis that silver fibre enhanced textiles increase microcirculation and doing so, increase body temperature, decrease feelings of cold and decrease complications of impaired microcirculation including complaints of Raynaud's phenomenon and digital ulcers. Therefore, this study aims to evaluate the benefits of silver fibre enhanced gloves in patients with Raynaud's phenomenon secondary to systemic

sclerosis.

## **Study objective**

To determine the efficacy of silver enhanced gloves in decreasing burden of Raynaud's phenomenon in patients with systemic sclerosis.

## **Study design**

Double-blind, randomised, cross-over trial. The trial is designed as a cross over trial to account for interindividual differences, weather changes during the trial period and influences of associations of the patients related to the colour of the gloves.

## **Intervention**

The study will be a double-blinded study on 100 adult patients with systemic sclerosis. All patients will wear both normal gloves and gloves containing silver fibres, each during a period of 6 weeks. Each type of gloves will be provided in 2 different colours. Patients will be randomised to: group I: starting with orange gloves containing silver fibers, followed by green gloves without silver fibers; group II: starting with orange gloves without silver fibers, followed by green gloves with silver fibers; group 3: starting with green gloves with silver fibers, followed by orange gloves without silver fibers; group 4: starting with green gloves without silver fibers, followed by orange gloves with silver fibers.

## **Study burden and risks**

Participation in this study has several associated burdens:

- Three additional study visits will be scheduled. These will take approximately 30-45 minutes and include completing the SHAQ, inspection of the hands and nailfoldcapillaroscopy examination.
- Participants are requested to complete an online questionnaire three times per week to document their complaints while wearing the gloves.
- Because the gloves used in the study will be dyed, wearing of the gloves could cause an allergic reaction to those who have a hypersensitivity to dyeing products.
- As the benefit of gloves containing silver threads has not been evaluated thus far, risks directly related to the intervention are not clear. In case of worsening of symptoms, possibly related to study gloves, participation will be ended.
- Patients will be offered reimbursement of travel costs.

## 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

- Age \* 18 years
- Diagnosis of Systemic sclerosis according to ACR/EULAR (American College of Rheumatology/European League Against Rheumatism) 2013 classification criteria (total score of \* 9, including a score of 3 for the RP item)
- Raynaud\*s attack frequency of at least 4 attacks per week on \* 3 different days and a Raynaud Condition score (RCS) at baseline of at least 34 (on a scale of 0-100)
- Vasoactive medication (Ca antagonists, ERA, PDE5 inhibitors) should be stable in the 2 weeks prior to the start of the trial
- written informed consent

## Exclusion criteria

- Past history of sympathectomy for Raynaud\*s phenomenon
- Current treatment with iloprost, or iloprost infusion < 6 weeks prior to screening
- Known allergy for dyes used in textiles
- Known allergy for silver fibre

## Study design

### Design

Study type:	Interventional
Intervention model:	Crossover
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Active
Primary purpose:	Treatment

### Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	08-12-2019
Enrollment:	85
Type:	Actual

### Medical products/devices used

Generic name:	Best4Hands silver gloves 9% silver
Registration:	Yes - CE intended use

## Ethics review

Approved WMO	
Date:	04-03-2019
Application type:	First submission

Review commission: METC Leiden-Den Haag-Delft (Leiden)  
metc-ldd@lumc.nl

Approved WMO  
Date: 16-10-2020  
Application type: Amendment  
Review commission: METC Leiden-Den Haag-Delft (Leiden)  
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Approved WMO  
Date: 26-03-2021  
Application type: Amendment  
Review commission: METC Leiden-Den Haag-Delft (Leiden)  
metc-ldd@lumc.nl

## Study registrations

### Followed up by the following (possibly more current) registration

No registrations found.

### Other (possibly less up-to-date) registrations in this register

ID: 20637  
Source: Nationaal Trial Register  
Title:

### In other registers

Register	ID
CCMO	NL67974.058.18
Other	Trial NL7904
OMON	NL-OMON20637

## Study results

Date completed: 11-06-2021

Actual enrolment: 85

### Summary results

Trial is ongoing in other countries