The effect of gloves containing silver fibre on burden caused by Raynaud’s phenomenon in patients with systemic sclerosis

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON20637

Source
Nationaal Trial Register

Brief title
HANDS ON

Health condition

Systemic sclerosis (SSc) is a connective tissue disease that is characterized by microvasculopathy, a disturbed immune system and fibrosis of the skin and internal organs. Raynaud’s phenomenon (RP) is often the first symptom of SSc and is experienced by >90% of the patients with SSc. RP is characterized by reversible and episodic attacks of vasospasm in the small arteries and arterioles of mostly the fingers and toes. The attacks are mostly triphasic, starting with pallor (white), followed by cyanosis (blue) and lastly followed by erythema (red). Emotional stress and cold are the main triggers for these attacks. Furthermore, RP secondary to SSc is linked with vascular changes, resulting in narrowing of the blood vessels and blood flow impairment.
RP strongly influences the quality of life and improvements in RP have been linked to better quality of life.

Sponsors and support

Primary sponsor: Leiden University Medical Center, Haga hospital The Hague, Maasstad

Rotterdam.
Source(s) of monetary or material Support: Skafit medical bv.

Intervention

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

Rationale: 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.
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.
Study population: Patients > 18 years with Raynaud's phenomenon secondary to systemic sclerosis will be included in this trial. The Raynaud Condition Score (RCS) at baseline should be > 34 and eligible patients should experience at least 4 attacks of Raynaud's per week. Patients who are currently treated with iloprost, and patients who have underwent a sympathectomy for Raynaud's in the past will be excluded from this trial.
Intervention: The study will be a double-blinded study on 80 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 gloves containing silver fibers (color 1), followed by gloves without silver fibers (color 2); group II: starting with gloves without silver fibers (color 1), followed by gloves with silver fibers (color 2); group 3: starting with gloves with silver fibers (color 2), followed by gloves without silver fibers (color 1); group 4: starting with gloves without silver fibers (color 2), followed by gloves with silver fibers (color 1). 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.
Main study parameters/endpoints: The primary endpoints of this study are the Raynaud Condition Score and the VAS for burden caused by Raynaud's. 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 objective

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 design

During the study participants will be sent 3 emails per week containing a link to a questionnaire (see appendix A) evaluating specific complaints during the past day including:
1. Raynaud Condition Score
2. Frequency of RP attacks
3. Mean duration of RP attacks
4. Impact of RP attacks on daily functioning (Visual Analog Scale)
5. Warmth of the hands (Visual Analog Scale)

Participants will visit the hospital at T=0 weeks, T=6 weeks and T=12 weeks. The following information is documented during these visits:
1. Skin / finger surface temperature (tip and base of the index finger)
2. Raynaud Severity Scale; VAS for burden related to RP
3. Number of Digital Ulcers, including number of incident digital ulcers
4. Capillary abnormalities and pattern, and capillary loss, using NCM (Nailfold Capillary Microscopy)
5. Scleroderma Health Assessment Questionnaire (SHAQ)

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 gloves containing silver fibers (colour 1), followed by gloves without silver fibers (colour 2); group II: starting with gloves without silver fibers (colour 1), followed by gloves with silver fibers (colour 2); group 3: starting with gloves with silver fibers (colour 2), followed by gloves without silver fibers (colour 1); group 4: starting with gloves without silver fibers (colour 2), followed by gloves with silver fibers (colour 1).

Contacts

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Eligibility criteria

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

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-11-2019
Enrollment:	80
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Yes

Plan description
Data will be handled confidential and anonymously in compliance with the Dutch Personal Data Protection Act (De Wet Bescherming Persoonsgegevens) and will comply with the EU General Data Protection Regulation (in Dutch: Uitvoeringswet AVG. UAVG). Patient data is coded. For this purpose, the existing biobank codes will be used. The code is not based on any of the patient’s characteristics. Only the investigators of this study have access to the identity of the patient linked to the code. All data will be inserted double, to avoid mistakes. All coded source data will be saved and processed in the online protected database program Castor.
Data can only be traced back to the participant with an encryption key that remains safely stored in the local research institute. Also, data cannot be traced back to the specific participants in reports and publications about the study. The data must be kept for 15 years

at the research location.
Some people can access the data at the research location: study team, LUMC monitors, the Medical Ethical Committee (MEC) of the LUMC and the Health and Youth Care Inspectorate (part of the Ministry of Health, Welfare and Sport).
Participants can withdraw their consent to the use of the personal data at any time. This applies to this study and, if applicable, also to use for future research. Study data collected until the moment the participant withdraws the consent will still be used in the study. For general information about the participants rights when processing personal data, the participant can consult the website of the Dutch Data Protection Authority. Also the data protection officer of the institution can be contacted.

Ethics review

Positive opinion

Date:	26-07-2019
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 55595
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL7904
CCMO	NL67974.058.18
OMON	NL-OMON55595

Study results

Summary results

N.A.