

# Manual lymph drainage in systemic sclerosis

<b>Submission date</b> 13/09/2010	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 08/12/2010	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 22/10/2021	<b>Condition category</b> Musculoskeletal Diseases	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

**Plain English summary of protocol**  
Not provided at time of registration

## Contact information

**Type(s)**  
Scientific

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## Additional identifiers

**Protocol serial number**  
N/A

## Study information

**Scientific Title**  
Manual lymph drainage improves upper limb oedema and hand function in patients with systemic sclerosis (SSC) in oedematous phase

**Study objectives**

In early systemic sclerosis (SSc), hand oedema is often present. This leads to hand pain and disability and, ultimately, to impaired perceived quality of life (QOL).

Manual lymph drainage (MLD) stimulates lymphatic system and reduces oedema.

This trial aims to evaluate the efficacy of MLD in reducing oedema and in improving functionality of the hands and perceived QoL in SSc patients in oedematous phase.

### **Ethics approval required**

Old ethics approval format

### **Ethics approval(s)**

The Ethics Committee of Azienda University Hospital Careggi (Comitato Etico Azienda Ospedaliera Universitaria Careggi [AOUC]) approved on the 27th September 2010 (ref: 514/2010)

### **Study design**

Single centre randomised controlled trial

### **Primary study design**

Interventional

### **Study type(s)**

Treatment

### **Health condition(s) or problem(s) studied**

Systemic sclerosis

### **Interventions**

Intervention group: 16 patients treated for 5 weeks (twice a week, 1 hour per session) with manual lymph drainage at upper limbs.

Control group: 16 patients asked to maintain their lifestyle for the duration of the study and to refrain from starting any new regular physical activity or exercise programs unrelated to the study.

All patients assessed at baseline, at end of treatment (after 5 weeks) and after 9 weeks of follow-up.

### **Intervention Type**

Other

### **Phase**

Not Applicable

### **Primary outcome(s)**

The following items assessed at baseline, at the end of treatment (after 5 weeks) and after 9 weeks of follow-up.

1. Hands volume assessed by volumetric test
2. Hands function evaluated by Hand Mobility in Scleroderma (HAMIS) test, assessed in both hands

### **Key secondary outcome(s)**

The following items assessed at baseline, at the end of treatment (after 5 weeks) and after 9 weeks of follow-up:

1. 4 visual assessment scales (VAS) 0-10 (0= best condition;10= worst condition) by which the patient self-assesses the entity (in the previous week) of

1.1. Hand oedema

1.2. Hand pain

1.3. The interference of hand oedema on the daily activities

1.4. The interference of hand pain on the daily activities.

2. Quality of life, assessed by the 36-item Short Form (SF-36) Health Survey and Health Assessment Questionnaire (HAQ)

### **Completion date**

15/03/2010

## **Eligibility**

### **Key inclusion criteria**

1. Both males and females, no age limits

2. Systemic sclerosis patients with oedematous hands fulfilling the American College of Rheumatology (ACR) criteria

### **Participant type(s)**

Patient

### **Healthy volunteers allowed**

No

### **Age group**

Other

### **Sex**

All

### **Key exclusion criteria**

1. Patients that do not meet the inclusion criteria

2. Ongoing infections and thrombosis

### **Date of first enrolment**

10/03/2009

### **Date of final enrolment**

15/03/2010

## **Locations**

### **Countries of recruitment**

Italy

**Study participating centre**  
**Villa Monna Tessa**  
Florence  
Italy  
50139

## **Sponsor information**

**Organisation**  
University of Florence (Italy)

**ROR**  
<https://ror.org/04jr1s763>

## **Funder(s)**

**Funder type**  
University/education

**Funder Name**  
University of Florence (Italy) - Department of Medicine

## **Results and Publications**

### **Individual participant data (IPD) sharing plan**

The current data sharing plans for this study are unknown and will be available at a later date

### **IPD sharing plan summary**

Not provided at time of registration