Manual lymph drainage in systemic sclerosis

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

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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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 sclerisis (SSC) in oedematour phase

Study objectives

In early systemic sclerosis (SSc), hand oedema is often present. This leads to hand pain and disability and, ultimately, to impaied 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 inferference 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

Αll

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

Study outputs

Output type Details Date created Date added Peer reviewed? Patient-facing?

Participant information sheet 11/11/2025 No Yes