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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

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format. Please use contact details below to request a patient information sheet

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 measure
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

Secondary outcome measures
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)

Overall study start date
10/03/2009

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

Age group
Other

Sex
Both

Target number of participants
32 patients affected with systemic sclerosis

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
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50139

Sponsor information

Organisation
University of Florence (Italy)

Sponsor details
Department of Medicine
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Sponsor type
University/education

Website
http://www.unifi.it/

ROR
https://ror.org/04jr1s763

Funder(s)

Funder type
University/education

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

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

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