

# Efficacy of the association of district specific and global rehabilitative techniques tailored for systemic sclerosis (SSc) patients

<b>Submission date</b> 15/12/2008	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 23/12/2008	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 23/12/2008	<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

### Contact name

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## Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N/A

## Study information

**Scientific Title**

The rehabilitation of systemic sclerosis: efficacy of the association of district specific and global rehabilitative techniques - a randomised controlled trial

**Study objectives**

Systemic sclerosis (SSc) is a systemic disease affecting the microvascular system and the connective tissue, causing important alterations of skin and internal organs and impairing the function of the heart, lung, kidney and peripheral nervous system. In SSc, the most important rehabilitative problems arise from skin induration and joint and muscle involvement often insufficiently responsive to a merely pharmacological approach. In fact, involvement of skin with progressive tissue fibrosis and retraction is a major condition of disability.

This trial aims to assess the short- and mid-term efficacy of an individualised rehabilitation programme specifically conceived and tailored for SSc and to set the basis of a specific rehabilitative approach to this chronic disease.

**Ethics approval required**

Old ethics approval format

**Ethics approval(s)**

Not provided at time of registration

**Study design**

Randomised controlled single centre trial

**Primary study design**

Interventional

**Secondary study design**

Randomised controlled trial

**Study setting(s)**

Other

**Study type(s)**

Treatment

**Participant information sheet****Health condition(s) or problem(s) studied**

Systemic sclerosis (SSc)

**Interventions**

20 SSc patients were enrolled and randomly assigned to Group A or Group B:

Group A (10 patients) was treated for a 9-week period (twice a week, 1 hour per session) with an individualised rehabilitation program whose composition partially differed from patient to patient on the basis of involved districts and patient's expectations. All patients were treated with hand and face rehabilitation. Hand lymphatic drainage and global methods such as aquatic and land-based global rehabilitation, also comprising respiratory exercises, and Ressayguier method were added when necessary.

Group B (10 patients) was the observational group, provided with education advices and medical information about SSc.

**Intervention Type**

Other

**Phase**

Not Applicable

**Primary outcome measure**

Improvement in disability and quality of life, assessed by the 36-item Short Form (SF-36) Health Survey and the Health Assessment Questionnaire (HAQ).

**Secondary outcome measures**

Hand and face involvement:

1. Hand Mobility in Scleroderma (HAMIS) test
2. Cochin Functional Hand Scale
3. Water Volumetric Test
4. Mouth functionality
5. Hand range of motion

**Overall study start date**

01/04/2007

**Completion date**

20/04/2008

## Eligibility

**Key inclusion criteria**

1. Diagnosis of systemic sclerosis according to the American College of Rheumatology (ACR) criteria
2. Facial skin score greater than 1
3. SSc hand involvement
4. No age limits

**Participant type(s)**

Patient

**Age group**

Other

**Sex**

Both

**Target number of participants**

20

**Key exclusion criteria**

Does not meet the inclusion criteria

**Date of first enrolment**

01/04/2007

**Date of final enrolment**

20/04/2008

## **Locations**

**Countries of recruitment**

Italy

**Study participating centre**

Viale Pieraccini 18

Florence

Italy

50139

## **Sponsor information**

**Organisation**

Italian Association for the Study of Systemic Sclerosis and Fibrotic Diseases (ASSMaF) (Italy)

**Sponsor details**

Viale Pieraccini 18

Florence

Italy

50139

**Sponsor type**

Research organisation

**Website**

<http://www.assmaf.org>

**ROR**

<https://ror.org/00feyy410>

## **Funder(s)**

**Funder type**

Research organisation

**Funder Name**

Italian Association for the Study of Systemic Sclerosis and Fibrotic Diseases (ASSMaF) (Italy)

**Results and Publications****Publication and dissemination plan**

Not provided at time of registration

**Intention to publish date****Individual participant data (IPD) sharing plan****IPD sharing plan summary**

Not provided at time of registration