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

Submission date
15/12/2008

Recruitment status
No longer recruiting

Registration date
23/12/2008

Overall study status
Completed

Last Edited
23/12/2008

Condition category
Musculoskeletal Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] 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

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

Primary study design
Interventional

Study design
Randomised controlled single centre trial

Study type(s)
Treatment

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

Key secondary outcome(s)

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

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

Healthy volunteers allowed
No

Age group
Other

Sex
All

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)

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

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration