Clinical Trial Protocol
Iranian Registry of Clinical Trials

15 Jul 2026

Evaluation of the effectiveness of eight weeks of pulmonary rehabilitation on cardiopulmonary parameters and quality of life in patients with scleroderma with pulmonary involvement

Protocol summary

Study aim

Evaluation of the effect of pulmonary rehabilitation on improving cardiac output, quality of life, dyspnea and spirometeric parameters including FVC and TLC

Design

Clinical trial with control group, with parallel groups, double-blind, randomized, phase 3, on 60 patients For randomization, the table of random numbers in a statistics book or computer-generated random numbers is used.

Settings and conduct

Aerobic and anaerobic exercises are given to all patients in 24 sessions and at the same time in the intervention group, pulmonary rehabilitation in patients is given by a sports medicine specialist in Shariati Hospital . Patients fill in the shortness of breath and quality of life questionnaire at the beginning and end of the study, and undergo a cardiopulmonary exercise test.The person performing the exercise test and the sports medicine specialist have no information about the patients' condition and the results of the tests.

Participants/Inclusion and exclusion criteria

Scleroderma patients according to Eular 2013 Less than 80 % or Ground Glass more than 10% in CT scan No drug change during the last 3 months Ability to do exercise ; Overlap syndrome or MCTD Contraindications for cardiopulmonary exercise test

Intervention groups

Scleroderma patients with pulmonary involvement Rehabilitation with aerobic and anaerobic exercise within 24 sessions and Simultaneously pulmonary rehabilitation for intervention group

Main outcome variables

Quality of Life; dyspnea; Cardiac output; FVC; TLC; VO2 max

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20151126025252N1**
Registration date: **2022-05-11, 1401/02/21**
Registration timing: **registered_while_recruiting**

Last update: **2022-05-11, 1401/02/21**
Update count: **0**

Registration date

2022-05-11, 1401/02/21

Registrant information

Name
hoda kavosi
Name of organization / entity
tehran university,rheumatology research center
Country
Iran (Islamic Republic of)
Phone
+98 21 8822 0065
Email address
h-kavosi@sina.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-12-22, 1400/10/01

Expected recruitment end date

2022-12-22, 1401/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Evaluation of the effectiveness of eight weeks of pulmonary rehabilitation on cardiopulmonary parameters and quality of life in patients with scleroderma with pulmonary involvement

Public title
Evaluation of the effectiveness of pulmonary rehabilitation on cardiopulmonary parameters and quality of life in patients with scleroderma with pulmonary involvement

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Patients with scleroderma according to the 2013 Eular criteria FVC less than 80 percent or CT involvement more than 10 percent No change in the medications taken by patients during the last 3 months These patients should have the ability to do exercise in the hospital and at home

Exclusion criteria:
Overlap syndrome and MCTD Inability to perform exercise Contraindications to CPET include:1) Unstable angina, 2) Uncontrolled arrhythmia, 3) Severe aortic stenosis,4) Arterial oxygen with pulse oximetry less than 85% in room air,5) Severe untreated arterial hypertension at rest (SBP200mmHg) (DBP120mmmHg), 6) Hypertrophic cardiomyopathy 7) Significant orthopedic disorder, 8) Mental disorder,9) Clinical signs of heart failure (pulmonary or peripheral edema) or EF less than 50%, 10) Severe valvular heart disease,11) Pulmonary hypertension >50 mmHg, 12) Acute pulmonary embolism - 13) Sinus tachycardia more than 120,14) Pericarditis, 15) Acute myocarditis, 16) Uncompensated heart failure, 17) Acute systemic disease or fever, 18) Coronary disease in the last 4 weeks -19) Metabolic disease such as acute thyroiditis

Age
From **18 years** old to **70 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Care provider
- Outcome assessor
- Data analyser

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
For random selection, patients are selected based on three steps and based on the randomization table including creating a random allocation sequence, hiding the allocation, and executing the random allocation sequence. Then, the table of random numbers in a statistical book or random numbers generated by the computer is used, by which patients are randomly placed in the intervention group.

Blinding (investigator's opinion)
Double blinded

Blinding description
Participant: Patients do not know whether they are in the intervention or control group and both groups are given exercise. Clinical caregiver: does not know the demographic results and information of patients' respiratory tests and CPET Consequence assessor: does not know the demographic status and type of intervention The researcher is not blind and the study is double-blind

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Gastroenterology and Liver Diseases Research Institute،Tehran University of Medi

Street address
Norht Kargar Ave, Shariati Hospital

City
Tehran

Province
Tehran

Postal code
1411713137

Approval date
2021-10-17, 1400/07/25

Ethics committee reference number
IR.TUMS.DDRI.REC.1400.033

Health conditions studied

1

Description of health condition studied
Systemic Scleroderma

ICD-10 code
M34.81

ICD-10 code description
Systemic sclerosis with lung involvement

Primary outcomes

1

Description
Shortness of breath

Timepoint
The beginning of the study before the intervention and after 8 weeks
Method of measurement
based on the St. George Questionnaire

2

Description
Quality of life
Timepoint
The beginning of the study before the intervention and after 8 weeks
Method of measurement
based on SHAQ questionnaire

3

Description
Cardiac output
Timepoint
The beginning of the study before the intervention and after 8 weeks
Method of measurement
based on echocardiography

4

Description
TLC: Total lung capacity
Timepoint
The beginning of the study before the intervention and after 8 weeks
Method of measurement
based on spirometry

5

Description
VO2MAX: Oxygen consumption
Timepoint
The beginning of the study before the intervention and after 8 weeks
Method of measurement
based on cardiopulmonary exercise test.

6

Description
FVC: forced Vital capacity
Timepoint
The beginning of the study before the intervention and after 8 weeks
Method of measurement
based on spirometry

Secondary outcomes

1

Description
Modified Rodnan Skin Score : A standard used to measure the degree of skin involvement, which measures the degree of skin tightness in 17 different areas of the body.. In terms of Thickness, it has four degrees: Normal = 0, Mild = 1, Moderate = 2, Severe = 3.
Timepoint
At the beginning of the study (before the intervention) and after 8 weeks (the end of the intervention)
Method of measurement
Physical Examination

Intervention groups

1

Description
Intervention Group: Half of the patients with scleroderma with pulmonary involvement in the study undergo CPET and VO2MAX are measured and then, in addition to routine treatments, undergo 24 sessions of aerobic and anaerobic exercise, as well as 8 weeks of pulmonary rehabilitation, and finally undergo CPET again, and patients' cardiopulmonary parameters will be evaluated. All patients complete the SHAQ shortness of breath and quality of life questionnaire at the beginning and end of the study.
Category
Rehabilitation

2

Description
Control group: Half of the patients with scleroderma with pulmonary involvement in the study undergo CPET and VO2MAX are measured and then, in addition to routine treatments, undergo 24 sessions of aerobic and anaerobic exercise and finally undergo CPET again, and patients' cardiopulmonary parameters will be evaluated. All patients complete the SHAQ shortness of breath and quality of life questionnaire at the beginning and end of the study.
Category
Rehabilitation

Recruitment centers

1

Recruitment center
Name of recruitment center
Shariati Hospital
Full name of responsible person
Hoda Kavosi
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Full name of responsible person
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6th floor, Tehran University of Medical Sciences, Ghods St., Keshavarz Boulevard
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Phone
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vcr@tums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Tehran University of Medical Sciences
Proportion provided by this source
100
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact
Name of organization / entity
Tehran University of Medical Sciences
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Samira Salehi
Position
Rheumatology Fellowship
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD
There is no plan to publish the data independently and the data will be provided only at the request of the publisher of the article.

Study Protocol
No - There is not a plan to make this available

Statistical Analysis Plan
No - There is not a plan to make this available

Informed Consent Form
No - There is not a plan to make this available

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code
No - There is not a plan to make this available

Data Dictionary
No - There is not a plan to make this available

Title and more details about the data/document
Items where patient information is known will not be published, but work results will be published along with statistical items

When the data will become available and for how long
after article publishing

To whom data/document is available
The main executor of the project

Under which criteria data/document could be used
.Data will be provided only at the request of the article publisher, but no re-analysis of the data is allowed.

From where data/document is obtainable
Project manager: Dr. Heda Kavousi, Rheumatology Research Center, Shariati Hospital, Tehran

What processes are involved for a request to access data/document
Formal request and review by the main executor of the project

Comments