Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Determination of effect of N acetylcysteine on pulmonary function in patients with diffuse scleroderma

Protocol summary

Summary

Scleroderma is one of the most challenging diseases between rheumatologic disorders. This disease affects many organs like skin, gastrointestinal tract, respiratory, renal, genitourinary, cardiovascular and vascular structures. In patients with systemic sclerosis (SSc), interstitial lung disease (ILD) predicts increased mortality. It seems that antioxidant therapy might be efficacious in ILD treatment. In this study we use NAC before lung involvement for better evaluation of its effect on progression of fibrosis.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014012616367N1**
Registration date: **2014-12-04, 1393/09/13**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2014-12-04, 1393/09/13

Registrant information

Name
Samrad Mehrabi
Name of organization / entity
Shiraz University of Medical Sciences
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Iran (Islamic Republic of)
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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Shiraz University of Medical Sciences

Expected recruitment start date

2014-03-06, 1392/12/15

Expected recruitment end date

2014-11-06, 1393/08/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Determination of effect of N acetylcysteine on pulmonary function in patients with diffuse scleroderma

Public title

Effect of N acetylcysteine on pulmonary function in patients with scleroderma

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Cases of diffuse scleroderma who fulfilled the ACR criteria for systemic sclerosis that diagnosis of their disease was made less than one year ago; No evidence of fibrosis in high rsolution CT scan (HRCT) Exclusion criteria: Lung involvement (deterioration of disease); Not properly usage of drug; Not regularly visits by cases in intervals and appointments that were determined for them; Not toleration of drug or probable allergic reactions to it (very rare reports); Clinical or serologic evidence of other collagen vascular disease; History of exposure to known fibrogenic agents; Previous use of immunosuppressive or corticosteroid therapy for a minimum of 6 months before entering the study.

Age

From **18 years** old to **100 years** old

Gender
Both

Phase
2-3
Groups that have been masked
No information
Sample size
Target sample size: **24**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Double blinded
Blinding description
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Shiraz University of Medical Sciences
Street address
Central building of Shiraz University of Medical Sciences- Zand Ave
City
Shiraz
Postal code
14336 - 71348
Approval date
2014-05-14, 1393/02/24
Ethics committee reference number
CT-P-9350-5900

Health conditions studied

1

Description of health condition studied
lung involvement in scleroderma
ICD-10 code
M34.8
ICD-10 code description
Respiratory disorders in other diffuse connective tissue disorders (systemic sclerosis)

Primary outcomes

1

Description
Total lung capacity
Timepoint
At the beginning and 6 months following start of intervention
Method of measurement
Body plethysmography measured by litre

2

Description
Diffusing capacity
Timepoint
At the beginning and 6 months following start of intervention
Method of measurement
DLCO ml/min

3

Description
Vital capacity
Timepoint
At the beginning and 6 months following start of intervention
Method of measurement
Body plethysmography

Secondary outcomes

1

Description
Adverse drug/placebo reaction
Timepoint
Every 2 months
Method of measurement
Ask from the patient

Intervention groups

1

Description
Intervention group: Tablets of Nacetylcysteine (NAC) are product of IRAN and 600mg. Therapy is with 1200 mg NAC daily that divided two times a day for six months.
Category
Treatment - Drugs

2

Description
Control group: Placebo will be given 2 times daily for 6 months.
Category
Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center
Scleroderma clinic
Full name of responsible person
Samrad Mehrabi
Street address
Hafez hospital, Chamran Blvd
City
Shiraz

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for research, Shiraz University of Medical Sciences
Full name of responsible person
Seyed Basir Hashemi
Street address
Vice chancellor for research, 7th floor, Central building of SUMS, Zand Ave
City
Shiraz
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice chancellor for research, Shiraz University of Medical Sciences
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

Contact
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty