Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Therapeutic effects of Ginkgo biloba on ischemic manifestations of scleroderma in extremities

Protocol summary

Summary

The aim of this randomized double blind study is to assess the effect of Ginkgo biloba on the ischemic manifestations of scleroderma in extremities. A total of fifty patients with scleroderma and raynaud's phenomenon will be randomly assigned into two groups of 25 each. The patients in one group will receive Ginkgo biloba (Tolidaru Pharmaceutical Company) 40mg tds for 3 months while in control group will receive placebo. Raynaud's Condition Score and Score Modified Rodnan Skin will be evaluated at the end of months 1, 2, and 3 and compared between groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201103062053N1**
Registration date: **2011-03-06, 1389/12/15**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2011-03-06, 1389/12/15

Registrant information

Name

Seideh Zahra Mirfeizi

Name of organization / entity

Mashhad University of Medical Sciences and Health Services

Country

Iran (Islamic Republic of)

Phone

+98 51 1846 1781

Email address

mirfeiziz@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research of Mashhad University of Medical Sciences and Health Services

Expected recruitment start date

2009-09-23, 1388/07/01

Expected recruitment end date

2011-06-20, 1390/03/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Therapeutic effects of Ginkgo biloba on ischemic manifestations of scleroderma in extremities

Public title

Therapeutic effects of Ginkgo biloba on ischemic manifestations of scleroderma in extremities

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: suffering from scleroderma, suffering from Raynaud's phenomenon, primary level of education, age more than 18 and less than 50 years old, signing the informed consent Exclusion criteria: consumption of use anticoagulants, consumption of NSAIDs, consumption of mono amino Oxidase inhibitors

Age

From **18 years** old to **50 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size
Target sample size: **50**
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
Mashhad University of Medical Sciences and Health Services
Street address
Ghoreishi Building, Daneshgah St, PO Box:951
City
Mashhad
Postal code
Approval date
2009-01-28, 1387/11/09
Ethics committee reference number
87176

Health conditions studied

1

Description of health condition studied
Scleroderma
ICD-10 code
M34
ICD-10 code description
Progressive Systemic Sclerosis

Primary outcomes

1

Description
Stiffness of the skin
Timepoint
Every months till 3 month
Method of measurement
Modified Rodnan Skin Score

2

Description
Raynaud's Condition
Timepoint
before treatment and at the end of months 1 , 2 , 3
Method of measurement
Raynaud's Condition Score

Secondary outcomes

1

Description
Interval of Raynaud's attack
Timepoint
every month till 3 month
Method of measurement
Patient examination and his/her statement about the condition of his/ her sickness.

Intervention groups

1

Description
Ginkgo biloba, Oral Tab 40 mg, Tds , for 3 months
Category
Treatment - Drugs

2

Description
Placebo, Oral Tab , Tds , for 3 months
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Emam Reza Hospital
Full name of responsible person
Street address
City
Mashhad

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice Chancellor for Research of Mashhad University of Medical Sciences and Health Services
Full name of responsible person
Vice President for Research (Jalil Tavakol Afshari Ph.D.)
Street address
Ghoreishi Building, Daneshgah St, PO Box:951
City
Mashhad
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 of Mashhad University of Medical Sciences and Health Services

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

Name of organization / entity

Mashhad University of Medical Sciences and Health Services

Full name of responsible person

Mohamad Hassan Jokar

Position

Associated Professor/Sub-specialty in Rheumatology

Other areas of specialty/work

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Web page address

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