

# 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

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Associated Professor/Sub-specialty in Rheumatology

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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*

**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Mashhad University of Medical Sciences and Health Services

**Full name of responsible person**

Mohamad Hassan Jokar

**Position**