

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 May 2026

Evaluating the effect of tropical sildenafil gel on incidence and severity of Raynaud's Phenomenon Attacks in patients with systemic sclerosis: A double blinded randomized clinical trial

Protocol summary

Study aim

Determining the effect of topical sildenafil gel on the occurrence of Raynaud's phenomenon and severity of symptoms in patients with systemic scleroderma(SS) in a double-blind clinical trial study.

Design

Clinical trial with control group, with parallel groups, double-blind, randomized, phase 3 on 70 patients. Sealed cards are used in the randomization method.

Settings and conduct

Patients with SS with skin involvement referring to Shahrekord rheumatology clinic are included in the study. Before entering the study, the patients will be visited once and their pain intensity and quality of life will be evaluated. They will also undergo nailfold capillaroscopy. This study will be done in a double-blind manner; In this way, first, all gels (sildenafil and placebo) will be coded by the clinical pharmacist and will be delivered to the researcher following the patient. Each patient will be followed up with a code that the content of the medicine he received will not be known until the end of the study. After two weeks have passed They will be visited again and evaluated in terms of pain intensity, quality of life and NF.

Participants/Inclusion and exclusion criteria

People diagnosed with SS according to the American College of Rheumatology classification criteria or LeRoy and Medsger criteria and skin involvement limited to fingers, hands, face, forearms and foot.

Intervention groups

Patients in both groups (Sildenafil 1% and placebo) will be used topically every 12 hours. The length of the treatment period for each patient is 14 days and it will end if the patient recovers completely and reaches the end point of the treatment. It should be noted that the routine treatment of patients in both groups will be the same and will be based on the latest relevant guidelines.

Main outcome variables

Pain intensity, quality of life and nailfold capillaroscopy

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20240203060886N1**

Registration date: **2024-02-22, 1402/12/03**

Registration timing: **prospective**

Last update: **2024-02-22, 1402/12/03**

Update count: **0**

Registration date

2024-02-22, 1402/12/03

Registrant information

Name

Alireza Rostamian

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 38 3222 0016

Email address

alireza_rostamian@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-03-05, 1402/12/15

Expected recruitment end date

2024-06-19, 1403/03/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Evaluating the effect of tropical sildenafil gel on incidence and severity of Raynaud's Phenomenon Attacks in patients with systemic sclerosis: A double blinded randomized clinical trial

Public title
Evaluating the effect of tropical sildenafil gel on incidence and severity of Raynaud's Phenomenon Attacks in patients with systemic sclerosis: A double blinded randomized clinical trial

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Age over 18 and under 75 years Patients with systemic sclerosis diagnosed by ACR criteria or LeRoy, Medsger Willingness to participate in the clinical trial Absence of MI, stroke or cardiac arrhythmia in recent 6 month Skin involvement limited to fingers, hands, face, forearms and feet
Exclusion criteria:
History of CKD (Creatinine clearance under 30 ml/minute) or cirrhosis (Child-Pugh class C) Overlap syndrome Hypersensitivity to topical sildenafil

Age
From **18 years** old to **75 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **70**

Randomization (investigator's opinion)
Randomized

Randomization description
By simple randomization, an envelope with a hidden card (35 group 1 and 35 group 2) will be selected for each person eligible to enter the study, and each patient will be assigned to the intervention or placebo group. Only the statistician and the clinical pharmacist will know the contents of each card and medicine received, and the shape, smell, color and other physical properties of the placebo will be similar to the medicine received by the intervention group.

Blinding (investigator's opinion)
Double blinded

Blinding description
This study will be done in a double-blind manner; In this way, first, all gels (sildenafil and placebo, which are completely similar in terms of shape, color, smell, and

consistency) will be coded by the clinical pharmacist and will be delivered to the researcher following the patient based on the block in which the patient is located. Each patient will be followed up with a code that is not known about the content of the medicine he received until the end of the study.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of the School of Medicine, Shahrekord University of Medical Sciences

Street address

Headquarters of Shahrekord University of Medical Sciences, Kashani Street, Shahrekord, Chaharmahal va Bakhtiary, Iran

City

Shahrekord

Province

Chahar-Mahal-va-Bakhtiari

Postal code

8815713471

Approval date

2024-01-03, 1402/10/13

Ethics committee reference number

IR.SKUMS.MED.REC.1402.082

Health conditions studied

1

Description of health condition studied

systemic sclerosis

ICD-10 code

M34

ICD-10 code description

Systemic sclerosis [scleroderma]

Primary outcomes

1

Description

severity of pain

Timepoint

Measurement of pain severity before the intervention and 2 and 6 weeks after the intervention

Method of measurement

Visual Analogue Scale (VAS) Questionnaire

2

Description

quality of life

Timepoint

Measuring different aspects of quality of life before the intervention and 2 and 6 weeks after the intervention

Method of measurement

The World Health Organization Quality of Life Brief Version (WHOQOL-BREF)

3

Description

Capillaroscopy of the nail bed of patients

Timepoint

before the intervention and 2 and 6 weeks after the intervention

Method of measurement

nailfold capillaroscope

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Taking Sildenafil 1% gel 15 grams (under the brand name Erecgel produced by Pishgam Daru Novin Pharmaceutical Company) every 8 hours

Category

Treatment - Drugs

2

Description

Control group: Placebo consumption (the base of the placebo made by the pharmaceutical company will include isopropyl myristate, surfactant and co-surfactant and distilled water, and in terms of shape, consistency, color and smell are the same as Sildenafil) every eight hours

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahrekord Hajar hospital

Full name of responsible person

Alireza Rostamian

Street address

Parastar street

City

shahrekord

Province

Chahar-Mahal-va-Bakhtiari

Postal code

8816754633

Phone

+98 38 3222 5505

Fax

+98 38 3224 3715

Email

alireza_rostamian@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahre-kord University of Medical Sciences

Full name of responsible person

Seyed-Mohammad Omrani

Street address

Parastar street

City

Shahrekord

Province

Chahar-Mahal-va-Bakhtiari

Postal code

8813833435

Phone

+98 935 682 4034

Email

alireza_rostamian@yahoo.com

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Shahre-kord 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

Shahre-kord University of Medical Sciences

Full name of responsible person

Alireza Rostamian

Position

resident

Latest degree

Medical doctor

Other areas of specialty/work

Internal Medicine

Street address

Parastar street

City

Shahrekord

Province

Chahar-Mahal-va-Bakhtiari

Postal code

8816754633

Phone

+98 38 3222 5055

Email

alireza_rostamian@yahoo.com

Person responsible for scientific inquiries

Contact**Name of organization / entity**

Shahre-kord University of Medical Sciences

Full name of responsible person

Mohammad Mosavi

Position

Associate professor

Latest degree

Subspecialist

Other areas of specialty/work

rheumatology

Street address

Parastar street

City

Shahrekord

Province

Chahar-Mahal-va-Bakhtiari

Postal code

8816754633

Phone

0098383220016

Email

m_mousavi50@yahoo.com

Person responsible for updating data

Contact**Name of organization / entity**

Shahre-kord University of Medical Sciences

Full name of responsible person

Alireza Rostamian

Position

resident

Latest degree

Medical doctor

Other areas of specialty/work

Internal Medicine

Street address

Parastar street

City

Shahrekord

Province

Chahar-Mahal-va-Bakhtiari

Postal code

8816754633

Phone

+98 38 3222 0016

Email

alireza_rostamian@yahoo.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

To share the data and documents of this research, only the information related to the main outcome will be shared. Also, files that can be published and do not violate people's privacy will be published

When the data will become available and for how long

The access period will start 6 months after the results are published

To whom data/document is available

Our data will only be available to researchers working in academic and scientific institutions .

Under which criteria data/document could be used

If there are conditions, all our data will be shared except personal information of people. The use of our data will only be allowed for similar research and review of our data by other researchers. All those who work in universities and scientific centers and decide to conduct similar research or check the accuracy of our data can access our data.

From where data/document is obtainable

In order to receive information, all eligible people can collect data by referring to the person in charge of the project. The contact methods are the email address alireza_rostamian@yahoo.com or the contact number 00989356824034

What processes are involved for a request to access data/document

To receive information after sending the request, the requests will be reviewed within 10 days. If the above conditions are met, the information will be sent to the provided email within 30 days at most.

Comments