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 capiloroscopy. 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 capiloroscopy

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

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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 و 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 ۴۰ ml/minute) or cirrhosis (Child-Pugh class C) Overlap syndrome Hypersnsitivity 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

Shhahrekord

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
Capiloroscopy of the nail bed of patients
Timepoint
before the intervention and 2 and 6 weeks after the intervention
Method of measurement
nailfold capiloroscope

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
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Sponsors / Funding sources

1

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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
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Other areas of specialty/work
Internal Medicine

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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