

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 Jul 2026

Evaluation of efficacy and safety of collagenase enzyme in the treatment of cutaneous sclerosis in patients with systemic scleroderma

Protocol summary

Study aim

Evaluation of efficacy and safety of collagenase enzyme in the treatment of cutaneous sclerosis in patients with systemic scleroderma.

Design

Clinical trial, randomized, Phase 2, non-blinded

Settings and conduct

This study was performed on 17 scleroderma patients referred to Hazrat Rasoul Hospital. The amount of facial wrinkles (opening mouse), scleroderma lesions of the face and around the lips and necrotic lesions of the fingers are examined. The blinding rule is not used.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 1- Patients should have at least one active scleroderma lesion. 2. Patients 20 to 70 years old. Exclusion criteria: 1- Patients who have received or inhaled oral prostanoids in the past 3 months. 2- Phosphodiesterase inhibitors have been used in the past month. 3- Take antibiotics 2 weeks before the study 4- Patients with common diseases such as diabetes, thyroid, cardiovascular complications such as ischemic heart disease.

Intervention groups

The intervention group is patients suffering from scleroderma lesions and receiving collagenase ointment as interferer, twice a day for three months. This study is a pilot study and before and after the patient is in control.

Main outcome variables

Qualitative and quantitative intensity of scleroderma

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20140624018210N11**

Registration date: **2021-12-12, 1400/09/21**

Registration timing: **prospective**

Last update: **2021-12-12, 1400/09/21**

Update count: **0**

Registration date

2021-12-12, 1400/09/21

Registrant information

Name

Elham Behrangi

Name of organization / entity

Iran University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-01-05, 1400/10/15

Expected recruitment end date

2022-04-17, 1401/01/28

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of efficacy and safety of collagenase enzyme in the treatment of cutaneous sclerosis in patients with systemic scleroderma

Public title

effect of collagenase enzyme in scleroderma

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients should have at least one active scleroderma lesion

Exclusion criteria:

Patients who have received or inhaled oral prostanoids in the past 3 months. Phosphodiesterase inhibitors have been used in the past month. Take antibiotics 2 weeks before the study.

Age

From **20 years** old to **70 years** old

Gender

Female

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **17**

Randomization (investigator's opinion)

N/A

Randomization description**Blinding (investigator's opinion)**

Not blinded

Blinding description**Placebo**

Not used

Assignment

Single

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics Committee of Iran University of Medical Sciences

Street address

Iran university -Hemat Highway

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Tehran

Province

Tehran

Postal code

19922347512

Approval date

2021-11-28, 1400/09/07

Ethics committee reference number

IR.IUMS.FMD.REC.1400.501

Health conditions studied**1****Description of health condition studied**

systemic scleroderma

ICD-10 code

M34

ICD-10 code description

Systemic sclerosis [scleroderma]

Primary outcomes**1****Description**

Qualitative intensity of scleroderma

Timepoint

Before treatment and 3 months after treatment

Method of measurement

Patient complaint, objective evaluation by a physician.

Secondary outcomes**1****Description**

Quantitative intensity of scleroderma

Timepoint

Before treatment, three months after treatment

Method of measurement

Determine the size of the lesions with visioface, determine the location and number of lesions

2**Description**

The rate of improvement of scleroderma

Timepoint

Before treatment, three months after treatment

Method of measurement

Patient satisfaction, visioface photography, physician diagnosis

3**Description**

Adverse events

Timepoint

Before treatment, three months after treatment

Method of measurement

Patient report, Physician diagnosis

Intervention groups**1****Description**

Intervention group: The intervention group is patients suffering from scleroderma. The intervention group will use collagenase ointment topically, twice a day for three months without interruption. It should be noted that the patient will receive routine treatments for this disease and will not be deprived of routine treatments.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Hazrat Rasool Akram Hospital

Full name of responsible person

Dr. Anushe Haghighi

Street address

Hazrat Rasool Akram Hospital, Niyayesh
avenue, Sattarkhan street, Tehran, Iran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

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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

Iran 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

Iran University of Medical Sciences

Full name of responsible person

Dr.Elham. Behranghi

Position

Associate Professor

Latest degree

Specialist

Other areas of specialty/work

Dermatology

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Dermatology ward, Hazrat Rasool Akram Hospital,
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Position

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Person responsible for updating data

Contact

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Full name of responsible person

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Resident

Latest degree

Medical doctor

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Not applicable