

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Effect of Grape seed oil (Grapex) on wound healing in patients with scleroderma

Protocol summary

Study aim

The effect of grape seed oil (Grapex) in wound healing of scleroderma patients

Design

Clinical trial with control group, with parallel groups, double-blind, randomized, phase 3 on 40 patients. Excel software rand function was used for randomization.

Settings and conduct

The present study was a double-blind clinical trial on scleroderma patients referred to the rheumatology clinic of Golestan hospital in Ahvaz. The patients, the intervener, and the person reviewing the results did not know what group the individuals were in, and the study was double-blind.

Participants/Inclusion and exclusion criteria

Inclusion criteria: presence of at least one active wound due to scleroderma (diffuse / limited), age 20 to 70 years, patients' consent. Exclusion criteria: Allergy (including allergy to grapes and their compounds), the presence of comorbidities including diabetes, thyroid disorders, and cardiovascular disease, addiction to alcohol or drugs, smoking, intake of prostanoids (any form) at least in the last 3 months, receiving antibiotics 2 weeks before the start of the study, moderate to severe liver disorders or increased aminotransferase levels more than 3 times, the presence of any type of malignancy, pregnancy and lactation, unwillingness to participate in the study

Intervention groups

Intervention group: Grapex 2% cream prepared from the School of Pharmacy was used twice a day for 4 weeks on the surface of their wounds. Control group: The second group of placebo (cream with similar composition except the main ingredient, ie grape seed extract prepared from Ahwaz School of Pharmacy) was given with the same duration of the intervention group

Main outcome variables

Wound size

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20201010048984N1**

Registration date: **2020-10-23, 1399/08/02**

Registration timing: **retrospective**

Last update: **2020-10-23, 1399/08/02**

Update count: **0**

Registration date

2020-10-23, 1399/08/02

Registrant information

Name

Marya. ghanavati

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 61 8670 5503

Email address

maryam.ghanavati2020@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-05-22, 1398/03/01

Expected recruitment end date

2020-07-25, 1399/05/04

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of Grape seed oil (Grapex) on wound healing in patients with scleroderma

Public title

Effect of Grape seed oil (Grapex) on scleroderma wound healing

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Existence of at least one active wound due to scleroderma (diffuse / limited) Age 20 to 70 years Patient satisfaction

Exclusion criteria:

Existence of allergy and sensitivity to grapes and their compounds, Existence of comorbidities including diabetes, thyroid disorders, and cardiovascular disease Addiction to alcohol, cigarettes and any drugs Getting prostanoids (both inhaled and taken) for at least the last 3 months Take antibiotics 2 weeks before the start of the study Moderate to severe hepatic impairment or elevated aminotransferase levels more than 3 Existence of any kind of malignancy Pregnancy and lactation Reluctance to participate in the study

Age

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

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients were divided into two groups A and B. Block randomization methods were used. The size of the block was four and in each block 2 patient in group A and 2 patient in group B were assigned. The order of groups A and B within each block was determined randomly using function (RAND) in Excel software.

Blinding (investigator's opinion)

Double blinded

Blinding description

Patients and the interventionist and the person examining the results did not know what group the individuals were in, and the study was double-blind.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics committee of Ahwaz Jundishapur University of Medical Sciences (AJUMS)

Street address

Khuzestan Province, Ahvaz

City

Ahvaz

Province

Khuzestan

Postal code

6135715794

Approval date

2019-03-16, 1397/12/25

Ethics committee reference number

IR.AJUMS.REC.1397.948

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

scleroderma

ICD-10 code

M34

ICD-10 code description

Systemic sclerosis [scleroderma]

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

Wound size

Timepoint

Every 2 weeks (end of the second week and the fourth week)

Method of measurement

Wound ruler

Secondary outcomes

empty

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

Intervention group: Grapex 2% cream prepared from the School of Pharmacy was used twice a day for 4 weeks on the surface of the wounds.

Category

Treatment - Drugs

2**Description**

Control group: The second group of placebo (cream with similar composition except the main ingredient, ie grape seed extract prepared from Ahwaz School of Pharmacy) was given with the same duration of the intervention group

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Rheumatology Clinic of Golestan Hospital, Ahvaz

Full name of responsible person

Maryam Ghanavati

Street address

Ahvaz, Farvardin Blvd., Golestan hospital

City

Ahvaz

Province

Khuzestan

Postal code

6135715794

Phone

+98 61 3374 3001

Email

Golestanjpsital@yahoo.com

Web page address**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Ahvaz University of Medical Sciences

Full name of responsible person

Dr Mohammad Badavi

Street address

Ahvaz, Golestan Boulevard

City

Ahvaz

Province

Khuzestan

Postal code

6135715794

Phone

+98 61 3374 3001

Email

Info@Ajums.Ac.Ir

Grant name

Ahvaz Jundishapur University of Medical Sciences

Grant code / Reference number

MPRC-9731

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

Yes

Title of funding source

Ahvaz 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**

Ahvaz University of Medical Sciences

Full name of responsible person

Maryam Ghanavati

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Internal Medicine

Street address

Ahvaz, Golestan Boulevard

City

Ahvaz

Province

Khuzestan

Postal code

6135715794

Phone

+98 61 3374 3001

Email

Maryam.ghanavati2020@gmail.com

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

Ahvaz University of Medical Sciences

Full name of responsible person

Maryam Ghanavati

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Internal Medicine

Street address

Ahvaz, Golestan Boulevard

City

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Province

Khuzestan

Postal code

6135715794

Phone

+98 61 3374 3001

Email

Maryam.ghanavati2020@gmail.com

Email

Maryam.ghanavati2020@gmail.com

Person responsible for updating data

Contact

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

Maryam Ghanavati

Position

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City

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Province

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Phone

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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

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