Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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
Khouzestan
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

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Ahvaz, Farvardin Blvd., Golestan hospital

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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

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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

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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