

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 Jul 2026

Evaluation of efficacy of intramuscular injection of pantothenic acid in patients with mild to moderate acne referred to dermatology clinics

Protocol summary

Study aim

Determination of the effect of injectable pantothenic acid in the treatment of mild to moderate acne

Design

A controlled, parallel-group, single-blind, randomized, phase 3 clinical trial on 60 patients. Random Allocation software is used for randomization

Settings and conduct

This study is conducted on patients with mild and moderate acne who refer to skin clinics of Shiraz University of Medical Sciences. Patients are randomly divided into two groups. Blinding is performed only at the level of the outcome assessor. The first group is treated with dexpantenol 500 mg ampoule, one intramuscular injection, and adapalene gel per week. The second group will only be treated with adapalene gel topically every other night.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 1. Patients with mild to moderate acne, 2. Patients have not received any systemic treatment in the last month and have not received any local treatment in the last two weeks 3. Married women agreed to use physical methods of contraception such as condoms and IUDs during the study. Exclusion criteria: 1- pregnant and lactating women 2- patients with polycystic ovary syndrome 3- use of herbal medicines 4- lack of consent to continue the study 5- history of allergy to the study drug 6- allergy to adapalene gel 7- impossibility Regular visits to check the response to treatment 8- Patients with severe acne 9- Existence of systemic disease including kidney and liver problems 10- Current use of food supplements for skin health

Intervention groups

The first group is treated with dexpantenol 500 mg ampoule manufactured by Actover pharmaceutical company, one intramuscular injection and adapalene gel per week. The second group will only be treated with adapalene gel topically every other night

Main outcome variables

Severity of acne using GAGS (Global Acne Grading System)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20150825023753N19**

Registration date: **2023-11-04, 1402/08/13**

Registration timing: **prospective**

Last update: **2023-11-04, 1402/08/13**

Update count: **0**

Registration date

2023-11-04, 1402/08/13

Registrant information

Name

Mohammad Mahdi Parvizi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 71 3212 5592

Email address

parvizim@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-11-06, 1402/08/15

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

Evaluation of efficacy of intramuscular injection of pantothenic acid in patients with mild to moderate acne referred to dermatology clinics

Public title

Evaluation of efficacy of intramuscular injection of pantothenic acid in patients with mild to moderate acne

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Patients with mild to moderate acne Patients have not received any systemic treatment in the last one month and have not received any local treatment in the last two weeks Married women who agree to use physical methods of contraception such as condoms and IUDs during the study

Exclusion criteria:

Pregnant and lactating women Patients with polycystic ovary syndrome Lack of consent to continue studying Use of herbal medicines History of allergy to the studied drug Allergy to adapalene gel Inability to visit regularly to check response to treatment Patients with severe acne Existence of systemic disease including kidney and liver problems Current use of dietary supplements for skin health

Age

From **16 years** old to **40 years** old

Gender

Both

Phase

3

Groups that have been masked

- Outcome assessor

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

By using random allocation software, consecutive permutation blocks with the size of 6 people in each block are made and the patients are divided into two groups A (first treatment method) and B (second treatment method).

Blinding (investigator's opinion)

Single blinded

Blinding description

Due to the clear difference in the treatment method and the different drug form in each study group, blinding is done only at the level of the outcome assessor.

Placebo

Not used

Assignment

Parallel

Other design features

In this plan, placebo is not used and each group will be prescribed a different medicine with the purpose of

treatment

Secondary Ids

empty

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

Ethics committee of Medical School of Shiraz University of Medical Sciences

Street address

Medical School of Shiraz University of Medical Sciences

City

Shiraz

Province

Fars

Postal code

7134845794

Approval date

2023-08-12, 1402/05/21

Ethics committee reference number

IR.SUMS.MED.REC.1402.208

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

Acne

ICD-10 code

L70.0

ICD-10 code description

Acne vulgaris

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

Acne severity

Timepoint

Base line, first month, second month

Method of measurement

Acne severity GAGS (Global Acne Grading System)

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

Quality of life of the patients

Timepoint

Base line, first month, second month

Method of measurement

Dermatology Quality of Life Index

2

Description

Acne count

Timepoint

Base line, first month, second month

Method of measurement

Counting the acne lesions

Intervention groups

1

Description

Intervention group: The first group is treated with dexpantenol 500 mg ampoule manufactured by Actover pharmaceutical company, one intramuscular injection and adapalene gel per week.

Category

Treatment - Drugs

2

Description

Control group: The second group will only be treated with adapalene gel topically every other night

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Emam Reza Dermatology Clinic

Full name of responsible person

Dr. Nasrin Saki

Street address

Emam Reza Poly Clinic, Zand Avenue

City

Shiraz

Province

Fars

Postal code

7134814734

Phone

+98 71 3212 7000

Email

nasrinsa85@yahoo.com

2

Recruitment center

Name of recruitment center

Shahid Faghihi Dermatology Clinic

Full name of responsible person

Dr. Nasrin Saki

Street address

Shahid Faghihi Hospital, Zand Avenue

City

Shiraz

Province

Fars

Postal code

71348466114

Phone

+98 71 3212 5592

Email

nasrinsa85@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Mohammad Hashem Hashempur, MD

Street address

7th floor, Vice Chancellor of Research, Shiraz University of Medical Sciences, Zand Blvd., Shiraz, Iran

City

Shiraz

Province

Fars

Postal code

7134814336

Phone

+98 71 3230 5410

Email

vcrdep@sums.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Shiraz 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

Shiraz University of Medical Sciences

Full name of responsible person

Fahimeh Mohammadi, MD

Position

Dermatology resident

Latest degree

Medical doctor

Other areas of specialty/work

Dermatology
Street address
Zand Avenue, Shahid Faghihi Hospital
City
Fars
Province
Fars
Postal code
7134846114
Phone
+98 71 3235 1087
Email
fahimeh.mohammadi8606@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Nasrin Saki, MD
Position
Associate professor
Latest degree
Specialist
Other areas of specialty/work
Dermatology
Street address
Zand Avenue, Shahid Faghihi Hospital
City
Shiraz
Province
Fars
Postal code
7134846114
Phone
+98 71 3235 1087
Email
nasrinsa85@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Mohammad Mahdi Parvizi, MD
Position

Associate professor
Latest degree
Ph.D.
Other areas of specialty/work
Dermatology
Street address
Zand Street
City
Shiraz
Province
Fars
Postal code
7134844119
Phone
+98 71 3235 1087
Email
mmparvizi@gmail.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

Demographic data and the result of the clinical trial

When the data will become available and for how long

One year later

To whom data/document is available

Researchers

Under which criteria data/document could be used

After publication of the extracted article of the clinical trial

From where data/document is obtainable

Sending Email to the researchers

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

Sending the request via email

Comments