

Clinical Trial Protocol

Iranian Registry of Clinical Trials

13 Jun 2026

Evaluation the effectiveness of Ziziphus spina-christi topical solution plus clindamycin 1% compared with Clindamycin1% plus placebo in mild to moderate acne

Protocol summary

Study aim

The aim of this study is to determine the efficacy of Cedar topical solution on reducing mild to moderate acne vulgaris symptoms in the facial area.

Design

Patients with mild to moderate acne are divided into two intervention and control groups by using Permuted block randomization method. The sample size is 55 in each group. The intervention group received topical cedar solution plus clindamycin 1% and the control group receiving topical placebo plus 1% clindamycin. The investigator and the patients are not aware of any type of treatment and the study is a double blind randomized clinical trial.

Settings and conduct

Patients who come to Behesht Clinic and have inclusion criteria randomly receive a package containing a solution of cedar or placebo, which are similar are similar in physical properties, shapes, colors, and odds, and they the inserted code. Patient and researcher have no information about drug or placebo.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 15-45 years old, both men and women
Suffering mild and moderate acne vulgaris in face
Exclusion criteria: pregnancy; lactating; polycystic ovary syndrome; using acnogenic medicines such as corticosteroids; humoral and antipsychotic medicines; other types of acne; skin allergy.

Intervention groups

patients with mild to moderate acne vulgaris, receive clindamycin 1% plus Cedar topical solution in the intervention group, and the topical solution of clindamycin 1% plus placebo in the control group randomly.

Main outcome variables

Comodon; postule and papule number

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20171112037409N1**

Registration date: **2018-05-04, 1397/02/14**

Registration timing: **registered_while_recruiting**

Last update: **2018-05-04, 1397/02/14**

Update count: **0**

Registration date

2018-05-04, 1397/02/14

Registrant information

Name

Rasoul Shakiba

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-05-04, 1397/02/14

Expected recruitment end date

2019-03-20, 1397/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation the effectiveness of Ziziphus spina-christi topical solution plus clindamycin 1% compared with Clindamycin1% plus placebo in mild to moderate acne

Public title

Effect of topical Cedar on Acne

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Subjects in age of 15 to 45 years old Chief complaint: mild to moderate Acne vulgaris subject willingness of herbal topical medicines use

Exclusion criteria:

pregnancy lactation History of polycystic ovary use of acnegenic medications such as corticosteroid, hormonal or anti-psychotic medications mechanical acne and gram-negative folliculitis History of dermal allergy

Age

From **15 years** old to **45 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator

Sample size

Target sample size: **110**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomized

Blinding (investigator's opinion)

Double blinded

Blinding description

Participant and investigator will be blinded to the treatment allocation throughout the course 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 Iran University of Medical Sciences

Street address

Hemat Highway next to Milad Tower, Iran University of Medical Sciences

City

Tehran

Province

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Postal code

1449614535

Approval date

2017-07-12, 1396/04/21

Ethics committee reference number

IR.IUMS.FMD.REC 1396.9221309202

Health conditions studied

1

Description of health condition studied

Acne vulgaris

ICD-10 code

L70.0

ICD-10 code description

Acne vulgaris

Primary outcomes

1

Description

Total lesion count

Timepoint

at the beginning of the study, 2nd, 6th and 8th weeks.

Method of measurement

counting the comedones, papules and pustules

2

Description

Severity of Acne

Timepoint

at the beginning of the study, 2nd, 6th and 8th weeks.

Method of measurement

Acne Severity Index

Secondary outcomes

1

Description

adverse effects including redness, burning and itching

Timepoint

2nd, 6th and 8th weeks of study.

Method of measurement

observation and physical examination

Intervention groups

1

Description

Intervention group: The topical solution of clindamycin (1%), with topical cedar solution, is applied 2 times a day for 6 weeks on the face.

Category

Treatment - Drugs

2**Description**

Control group: The topical solution of 1% Clindamycin plus placebo is applied 2 times a day for 6 weeks on face.

Category

Treatment - Drugs

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

Behesht clinical and Educational centre

Full name of responsible person

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

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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

Rasoul Shakiba

Position

Associate professor

Latest degree

Medical doctor

Other areas of specialty/work

Traditional Medicine

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Latest degree

Medical doctor

Other areas of specialty/work

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Phone**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