

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 May 2026

Comparison of the effects of topical spironolactone solution and topical clindamycin solution on mild to moderate acne vulgaris treatment in Sina hospital, Hamadan

Protocol summary

Study aim

Determining and comparing the effect of topical spironolactone solution with topical clindamycin solution in the treatment of mild to moderate acne

Design

A clinical trial with a control group, 80 patients, phase 3, double-blind, randomized by Block Randomization method

Settings and conduct

This study is done in patients diagnosed with acne vulgaris who attend to dermatology clinic of Sina hospital. Patients who met the inclusion criteria will be interviewed. All the patients' information such as age, sex, BMI, acne severity score, number and type of skin lesions (comedone, papule, pustule), and history of hormonal problems will be recorded in the checklist. patients will be divided into two treatment groups with the Block Randomization method. In order to avoid bias in this study, the researcher and the patient do not know the type of medicine assigned, and the study is conducted in a double-blind manner.

Participants/Inclusion and exclusion criteria

Inclusion Criteria : People with mild to moderate acne, age 18 years and above Exclusion Criteria : Pregnant and lactating women, known sensitivity to clindamycin, history of using oral isotretinoin, laser or chemical peeling in the last 6 months, history of taking oral estrogen compounds in the last 3 months, history of using retinoid and antibiotics in the past one month, a history of using antimicrobial soaps and topical exfoliants in the past two weeks, chronic skin diseases such as psoriasis, lichen planus, vitiligo, weak immune system or taking immunosuppressive drugs

Intervention groups

Intervention group: treatment with 2% spironolactone topical solution made by an experienced pharmacist twice a day for 3 months Control group: treatment with

2% clindamycin topical solution made by an experienced pharmacist twice a day for 3 months

Main outcome variables

Acne Severity

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220720055503N1**

Registration date: **2022-07-22, 1401/04/31**

Registration timing: **registered_while_recruiting**

Last update: **2022-07-22, 1401/04/31**

Update count: **0**

Registration date

2022-07-22, 1401/04/31

Registrant information

Name

Somayeh Zare

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 81 3825 3753

Email address

somi.0006@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-07-22, 1401/04/31

Expected recruitment end date

2023-07-22, 1402/04/31

Actual recruitment start date

empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison of the effects of topical spironolactone solution and topical clindamycin solution on mild to moderate acne vulgaris treatment in Sina hospital, Hamadan

Public title
Comparison of the effects of topical spironolactone solution and topical clindamycin solution on mild to moderate acne vulgaris treatment

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

People with mild to moderate acne 18 years old and above

Exclusion criteria:

Pregnant and lactating women Known hypersensitivity to clindamycin History of using oral isotretinoin, laser or chemical peeling in the last 6 months History of taking oral estrogen compounds in the last 3 months History of using retinoid or antibiotics during the last month History of using antimicrobial soaps or topical peels during the last two weeks Chronic skin diseases such as psoriasis, lichen planus, vitiligo Weakness of the immune system or the use of immunosuppressive drugs

Age
From **18 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Investigator
- Outcome assessor

Sample size
Target sample size: **80**

Randomization (investigator's opinion)
Randomized

Randomization description
Block randomization method was used for randomization. Participants are placed in blocks of 8. First, the block number is selected among the 8 balls (numbered 1 to 8) in the lottery container. The order of placement of people in group A or B in blocks 1 to 10 has already been determined randomly by the sealed envelope website.

Blinding (investigator's opinion)
Double blinded

Blinding description
The pharmacologist who is in charge of preparing the drugs knows what group A and group B drugs are, and she sticks the label A or B on the prepared drugs and delivers them to the researcher, so the participant, researcher and outcome evaluator are blind.

Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids
empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Hamedan University of Medical Sciences

Street address

Building 4, No. 22, Ostad Morad Hanife St., Honarestan Blv.

City

Hamedan

Province

Hamadan

Postal code

6516768845

Approval date

2022-06-26, 1401/04/05

Ethics committee reference number

IR.UMSHA.REC.1401.323

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

Acne Severity

Timepoint

Beginning of trial, 1 month, 2 months and 3 months after treatment

Method of measurement

Global Acne Grading System

Secondary outcomes

1

Description

Frequency and type of acne lesions

Timepoint

Beginning of trial,1 month,2 months and 3 months after treatment

Method of measurement

Counting type and number of lesions

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

Intervention group: Treatment with 2% spironolactone topical solution made by an experienced pharmacist twice a day for 3 months

Category

Treatment - Drugs

2**Description**

Control group: Treatment with 2% clindamycin topical solution made by an experienced pharmacist twice a day for 3 months

Category

Treatment - Drugs

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

Sina Hospital

Full name of responsible person

Bahareh Ebrahimi

Street address

Mirzadeh Eshghi Ave.

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Province

Hamadan

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6516848741

Phone

+98 81 3827 4192

Email

somi.0006@gmail.com

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

Hamedan University of Medical Sciences

Full name of responsible person

Reza Shokoohi

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Fahmideh Ave., Opposite Mardom Park

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Email

shokoohi@yahoo.com

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Hamedan 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**

Hamedan University of Medical Sciences

Full name of responsible person

Bahareh Ebrahimi

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Dermatology

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

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Full name of responsible person

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Position

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Latest degree

Specialist

Other areas of specialty/work

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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

All data after de-identification

When the data will become available and for how long

6 months after the results are published

To whom data/document is available

Researchers working in academic institutions

Under which criteria data/document could be used

The topic of the researcher's study is related to the topic of this study and has a code of ethics

From where data/document is obtainable

Somayeh Zare M.D. somi.0006@gmail.com Bahareh Ebrahimi M.D. b.ebrahimi.4362@gmail.com

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

Send the application, the title of the study and ethical documents via email, and after checking, the data will be emailed to her within one month at the latest

Comments**Person responsible for updating data****Contact****Name of organization / entity**

Hamedan University of Medical Sciences

Full name of responsible person

Bahareh Ebrahimi

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Dermatology

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