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.
City
Hamedan
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Hamadan
Postal code
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
Street address
Fahmideh Ave., Opposite Mardom Park
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Hamadan
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6516848741
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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 updating data

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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