Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Efficacy and safety of spironolactone 2% versus erythromycin 4% in treating patients with acne

Protocol summary

Study aim
Assessing the efficacy of topical spironolactone 2% versus erythromycin 4% in the treatment of acne

Design
Two arm parallel group randomised trial with blinded outcome assessment phase 2 on 90 patients. Block randomization would be used for sampling.

Settings and conduct
Acne patients referred to Razi Hospital in 1401-1402 who are approved based on the inclusion and non-inclusion criteria would be included in this clinical trial. After obtaining written consent from the patient and recording the history, clinical information would be collected in pre-prepared questionnaires. 3 groups and each group includes 30 patients will be selected. Patients should avoid using other drugs to cure acne during the study period. All solutions are kept in a similar bottle where the usage and storage conditions of the medicine are written. The name of the medicine is not written on the bottle. All patients should apply the solution twice a day (morning and night). This procedure continues for 12 weeks. The patient will visit the medical center for 3 sessions (0-6-12 weeks).

Participants/Inclusion and exclusion criteria
Inclusion: Aged 18-40 Acne diagnosis by a dermatologist Non-inclusion: Pregnancy or breastfeeding during the intervention history of internal diseases, including endocrine diseases causing acne alteration in diet and lifestyle during the study having consumed systemic therapy for acne in the last 4 weeks having consumed oral antibiotics in the last 3 months having consumed topical therapy for acne in the last 2 weeks having consumed isotretinoin, undertaken laser, and peeling in the last 6 months Photosensitivity severe or nodularis acne polycystic ovary syndrome

Intervention groups
1st group: spironolactone 2% solution 2nd group: erythromycin 4% solution 3rd group: spironolactone 2% and erythromycin 4% solution

Main outcome variables
Safety and efficacy of the treatments

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20181005041243N1**
Registration date: **2022-09-16, 1401/06/25**
Registration timing: **prospective**

Last update: **2022-09-16, 1401/06/25**
Update count: **0**

Registration date
2022-09-16, 1401/06/25

Registrant information

Name
Nika Kianfar

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 21 2285 7201

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N-kianfar@alumnus.tums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-11-10, 1401/08/19

Expected recruitment end date
2023-05-09, 1402/02/19

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Efficacy and safety of spironolactone 2% versus erythromycin 4% in treating patients with acne

Public title
Effect of spironolactone and erythromycin solution in treatment of acne

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Aged 18-40 Acne diagnosis by a dermatologist

Exclusion criteria:
Pregnancy or breastfeeding during the intervention history of internal diseases, including endocrine diseases causing acne alteration in diet and lifestyle during the study having consumed systemic therapy for acne in the last 4 weeks having consumed oral antibiotics in the last 3 months having consumed topical therapy for acne in the last 2 weeks having consumed isotretinoin, undertaken laser, and peeling in the last 6 months Photosensitivity severe or nodularis acne polycystic ovary syndrome

Age
From **18 years** old to **40 years** old

Gender
Both

Phase
2-3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **90**

Randomization (investigator's opinion)
Randomized

Randomization description
Individual blocks will be created without stratified randomization by statistical software. And another person (rather than the doctor-researcher-patient) would do the randomization. Accordingly, patients will receive each treatment based on the randomized sequence. Block sizes: 6 Actual list length: 90 block identifier, block size, sequence within block, treatment 1, 6, 1, Group B 1, 6, 2, Group A 1, 6, 3, Group C 1, 6, 4, Group A 1, 6, 5, Group C 1, 6, 6, Group B 2, 6, 1, Group B 2, 6, 2, Group A 2, 6, 3, Group C 2, 6, 4, Group C 2, 6, 5, Group B 2, 6, 6, Group A 3, 6, 1, Group B 3, 6, 2, Group C 3, 6, 3, Group C 3, 6, 4, Group A 3, 6, 5, Group B 3, 6, 6, Group A 4, 6, 1, Group A 4, 6, 2, Group C 4, 6, 3, Group A 4, 6, 4, Group B 4, 6, 5, Group C 4, 6, 6, Group B 5, 6, 1, Group C 5, 6, 2, Group C 5, 6, 3, Group B 5, 6, 4, Group B 5, 6, 5, Group A 5, 6, 6, Group A 6, 6, 1, Group A 6, 6, 2, Group C 6, 6, 3, Group C 6, 6, 4, Group B 6, 6, 5, Group A 6, 6, 6, Group B 7, 6, 1, Group C 7, 6, 2, Group A 7, 6, 3, Group A 7, 6, 4, Group B 7, 6, 5, Group C 7, 6, 6, Group B 8, 6, 1, Group A 8, 6, 2, Group A 8, 6, 3, Group C 8, 6, 4, Group B 8, 6, 5, Group B 8, 6, 6, Group C 9, 6, 1, Group B 9, 6, 2, Group C 9, 6, 3, Group A 9, 6, 4, Group A 9, 6, 5, Group B 9, 6, 6, Group C 10, 6, 1, Group A 10, 6, 2, Group A 10, 6, 3, Group B 10, 6, 4, Group C 10, 6, 5, Group C 10, 6, 6, Group B 11, 6, 1, Group A 11, 6, 2, Group B 11, 6, 3, Group C 11, 6, 4, Group A 11, 6, 5, Group B 11, 6, 6, Group C 12, 6, 1, Group A 12, 6, 2, Group C 12, 6, 3, Group A 12, 6, 4, Group B 12, 6, 5, Group B 12, 6, 6, Group C 13, 6, 1, Group A 13, 6, 2, Group B 13, 6, 3, Group A 13, 6, 4, Group C 13, 6, 5, Group B 13, 6, 6, Group C 14, 6, 1, Group B 14, 6, 2, Group B 14, 6, 3, Group A 14, 6, 4, Group C 14, 6, 5, Group A 14, 6, 6, Group C 15, 6, 1, Group C 15, 6, 2, Group B 15, 6, 3, Group A 15, 6, 4, Group B 15, 6, 5, Group C 15, 6, 6, Group A

Blinding (investigator's opinion)
Double blinded

Blinding description
The container containing the medicines will be without a drug name label and all the containers will be similar and indistinguishable. Another person out of the study will distribute the desired medicine to the patients based on the randomization sequence. Therefore, the physician, the outcome assessor, and the analyzer will remain unaware of the drug's content. According to the mentioned points, this study will be double-blind.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Tehran University of Medical Sciences

Street address
Vahdate-Eslami Square

City
Tehran

Province
Tehran

Postal code
11996

Approval date
2022-09-10, 1401/06/19

Ethics committee reference number
IR.TUMS.MEDICINE.REC.1401.442

Health conditions studied

1

Description of health condition studied
Acne
ICD-10 code
L70
ICD-10 code description
Acne

Primary outcomes

1

Description
Acne severity index
Timepoint
At the beginning of the study (before the start of the intervention) and 6 and 12 weeks after the start of trial
Method of measurement
Acne severity index (ASI) formula

2

Description
Patients' satisfaction with acne recovery
Timepoint
At the beginning of the study (before the start of the intervention) and 6 and 12 weeks after the start of trial
Method of measurement
Visual Analogue Scale

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group 1: spironolactone 2% solution
Category
Treatment - Drugs

2

Description
Intervention group 2: erythromycin 4% solution
Category
Treatment - Drugs

3

Description
Intervention group 3: spironolactone 2% solution شدی erythromycin 4% solution
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Razi hospital
Full name of responsible person
Safoura Shakoei nejad
Street address
Vahdate eslami St. Razi alley
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Tehran
Province
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Postal code
۱۱۹۹۶۶۳۹۱۱
Phone
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Email
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
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Email
dr.shakoei@gmail.com
Grant name
Grant code / Reference number
1401-2-101-58796
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Tehran 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
Tehran University of Medical Sciences

Full name of responsible person
Nika Kianfar

Position
Post doctorate position

Latest degree
Medical doctor

Other areas of specialty/work
Dermatology

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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
The data file information of the participants - study protocol - statistical analysis plan - informed consent form will be published after de-identification.

When the data will become available and for how long
The access period starts 6 months after the results are published

To whom data/document is available
Receiving data will be available for researchers working in academic and scientific institutions or people who are also engaged in industry

Under which criteria data/document could be used
In order to conduct scientific studies

From where data/document is obtainable
Dr. Nika Kianfar nika_kianfar@yahoo.com

What processes are involved for a request to access data/document
After sending the request by providing a logical reason, the data will be sent to the person within 2 weeks.

Comments