Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Effect of topical cream containing green tea and licorise extract as add-on therapy versus control group on the improvement of mild to moderate acne: a double-blind randomized clinical trial

Protocol summary

Study aim
To assess the effect of topical cream containing green tea and licorise extract as add-on therapy versus control group on the improvement of mild to moderate acne

Design
This is a Phase III double-blind randomized clinical trial with a control group, in which eligible patients will be randomly assigned to the intervention and control groups using block randomization.

Settings and conduct
This study will be conducted at the Sina Hospital in Hamadan city, involving 70 eligible patients with mild to moderate acne. The patients will be randomly assigned to the intervention and control groups through the block randomization. This trial will be double-blinded.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Age 12 to 70 years Mild to moderate acne for at least 6 months Exclusion criteria: Pregnancy or breastfeeding Acne lesions with infection The presence of other skin diseases at the same time

Intervention groups
Intervention group: Clindamycin topical solution 1% plus topical cream containing green tea extract and licorice twice a day for 8 weeks Control group: Clindamycin topical solution 1% plus base cream without green tea extract and licorice twice a day for 8 weeks

Main outcome variables
Primary outcome: Severity and extent of acne lesions, quality of life

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20120215009014N493**
Registration date: **2023-12-12, 1402/09/21**
Registration timing: **prospective**

Last update: **2023-12-12, 1402/09/21**
Update count: **0**

Registration date
2023-12-12, 1402/09/21

Registrant information
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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-12-26, 1402/10/05

Expected recruitment end date
2024-02-24, 1402/12/05

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Effect of topical cream containing green tea and licorise extract as add-on therapy versus control group on the improvement of mild to moderate acne: a double-blind

randomized clinical trial

Public title
Effect of topical cream containing green tea and licorise extract as add-on therapy versus control group on the improvement of mild to moderate acne
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Age 12 to 70 years Mild to moderate acne for at least 6 months
Exclusion criteria:
Pregnancy or breastfeeding Acne lesions with infection The presence of other skin diseases at the same time
Age
From **12 years** old to **70 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Outcome assessor

Sample size
Target sample size: **70**
Randomization (investigator's opinion)
Randomized
Randomization description
In this study, random assignment of patients to the intervention and control groups will be carried out using block randomization. To achieve this, four sheets of paper will be prepared - two with the name of the intervention and two with the name of the control. These paper sheets will be pooled and placed in a container. Patients will be selected one at a time without replacement, and for each patient, a paper sheet will be randomly drawn from the container. After each draw, the paper sheets will be returned to the container, and the process will be repeated until the desired sample size is reached.
Blinding (investigator's opinion)
Double blinded
Blinding description
Both the medications and placebos will have the same shape. Consequently, patients will remain unaware of the type of intervention they receive. Moreover, the randomization process will be conducted by a separate individual from the one who examines the patients, ensuring that the examining person remains unaware of the intervention. Therefore, the trial will be conducted as a double-blind study.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Hamadan University of Medical Sciences
Street address
Vice-chancellor for Research and Technology, Hamadan University of Medical Sciences, Fahmideh Ave
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Approval date
2022-12-31, 1401/10/10
Ethics committee reference number
IR.UMSHA.REC.1401.851

Health conditions studied

1

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

Primary outcomes

1

Description
Severity and extent of acne lesions
Timepoint
Before the intervention and in the fourth and eighth weeks after the intervention
Method of measurement
Based on the Global Acne Grading System (GAGS)

2

Description
Quality of life of patients
Timepoint
Before the intervention and in the fourth and eighth weeks after the intervention
Method of measurement
Using Dermatology Life Quality Index (DLQI)

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Clindamycin topical solution 1% plus topical cream containing green tea extract and licorice twice a day for 8 weeks
Category
Treatment - Drugs

2

Description
Control group: Clindamycin topical solution 1% plus base cream without green tea extract and licorice twice a day for 8 weeks
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Sina Hospital in Hamadan city
Full name of responsible person
Zahra Aziz Malayeri
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Sponsors / Funding sources

1

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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
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
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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