

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

28 May 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 licorise twice a day for 8 weeks Control group: Clindamycin topical solution 1% plus base cream without green tea extract and licorise 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

###### Name

Jalal Poorolajal

###### Name of organization / entity

Department of Epidemiology & Biostatistics Hamadan University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 81 1838 0090

###### Email address

poorolajal@umsha.ac.ir

##### 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

##### City

Hamadan

##### Province

Hamadan

##### Postal code

6517838695

#### 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

##### Street address

Sina Hospital, Mirzadeh Eshghi Ave.

##### City

Hamadan

##### Province

Hamadan

##### Postal code

6517838695

##### Phone

+98 81 3827 4184

##### Email

zahra.azizmly@gmail.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Hamedan University of Medical Sciences

##### Full name of responsible person

Dr. Reza Shokoohi

##### Street address

Hamadan University of Medical Sciences, Fahmideh Ave

##### City

Hamadan

##### Province

Hamadan

##### Postal code

6517838695

##### Phone

+98 81 3838 0717

#### Email

info.research@umsha.ac.ir

#### 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

Zahra Aziz Malayeri

##### Position

Student of Pharmacy

##### Latest degree

Medical doctor

##### Other areas of specialty/work

Medical Pharmacy

##### Street address

School of Pharmacy, Hamadan University of Medical Sciences, Fahmideh Ave.

##### City

Hamadan

##### Province

Hamadan

##### Postal code

6517838695

##### Phone

+98 81 3838 0572

##### Email

zahra.azizmly@gmail.com

## Person responsible for scientific inquiries

#### Contact

##### Name of organization / entity

Hamedan University of Medical Sciences

##### Full name of responsible person

Dr. Seyed Yaser Vafaei

##### Position

Pharmacologist

##### Latest degree

Medical doctor

##### Other areas of specialty/work

Medical Pharmacy

**Street address**

School of Pharmacy, Hamadan University of Medical Sciences, Fahmideh Ave.

**City**

Hamadan

**Province**

Hamadan

**Postal code**

6517838695

**Phone**

+98 81 3838 0572

**Email**

vafaei→\_y@yahoo.com

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

Hamedan University of Medical Sciences

**Full name of responsible person**

Dr. Jalal Poorolajal

**Position**

Professor of Epidemiology

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Epidemiology

**Street address**

School of Public Health, Hamadan University of Medical Sciences, Fahmideh Ave

**City**

Hamadan

**Province**

Hamadan

**Postal code**

6517838695

**Phone**

+98 81 3838 0090

**Email**

poorolajal@umsha.ac.ir

**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