

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

28 Jun 2026

### Evaluation of the effectiveness of the combination of Berberis integerrima root extract and Thyme essential oil in the treatment of acne vulgaris Compared to clindamycin

#### Protocol summary

##### Study aim

Evaluation of the effectiveness of the combination of Berberis integerrima root extract and Thyme essential oil in the treatment of acne vulgaris Compared to clindamycin

##### Design

Two arm parallel groups randomized trial with the control group

##### Settings and conduct

The study will be performed in Sedigheh Tahereh Research Center of Isfahan. Patients with inclusion criteria will be randomly assigned to drug or control groups. The sample size is 40 patients. For patients in the drug group, a topical solution of Berberis integerrima extract and thyme essential oil will be applied for four weeks, while for patients of the control group, clindamycin 1% topical solution will be used for four weeks. Before and at the end of the intervention, the number of lesions and their type and mGAGS (Modified Global Acne Grading scale) score will be recorded. Finally, the mentioned variables will be compared between the groups.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: mild to moderate acne vulgaris.  
Exclusion criteria: Receiving systemic anti-acne treatment or antiandrogen medicine during the last three months. Receiving oral anti-acne treatment or systemic antibiotics during the last month. Hepatic or renal disorder. Endocrine disorders. Receiving oral contraceptive during last one month. Other skin disorders or infections. Pregnancy. Lactation. Consumption of any drugs that induce acne. Alcohol or substance abuse.

##### Intervention groups

Intervention group: 5% Berberis integerrima extract and 1% thyme essential oil in 70% ethanol topical solution, for 28 days Control group: clindamycin 1% in 70%

ethanol topical solution, for 28 days

##### Main outcome variables

1. Percentage change in mGAGS score at the end of the intervention 2. Change the number of lesions at the end of the intervention 3. Change the number of lesions Divided into types at the end of the intervention

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20150721023282N21**

Registration date: **2021-11-07, 1400/08/16**

Registration timing: **prospective**

Last update: **2021-11-07, 1400/08/16**

Update count: **0**

##### Registration date

2021-11-07, 1400/08/16

##### Registrant information

##### Name

Rasool Soltani

##### Name of organization / entity

Isfahan University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 31 3792 7067

##### Email address

soltani@pharm.mui.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2021-12-21, 1400/09/30

**Expected recruitment end date**

2022-06-21, 1401/03/31

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Evaluation of the effectiveness of the combination of Berberis integerrima root extract and Thyme essential oil in the treatment of acne vulgaris Compared to clindamycin

**Public title**

Evaluation of the effectiveness of Berberis integerrima and Thyme essential oil in the treatment of acne

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

Mild acne vulgaris. Mild acne is defined as non-inflammatory lesions (comedones), a few inflammatory (papulopustular) lesions, without nodules and cysts. Moderate acne vulgaris. Moderate acne is defined as more inflammatory lesions, with or without comedones, without nodules and cysts.

**Exclusion criteria:**

Receiving systemic anti-acne treatment during last three months Receiving oral anti-acne treatment during last one month Receiving systemic antibiotics during last one month Receiving antiandrogen medicine during last three months Hepatic or renal disorder Endocrine disorders Receiving oral contraceptive during last one month Other skin disorders or infection Pregnancy Lactation Consumption of any drugs that induce acne Alcohol or substance abuse

**Age**

No age limit

**Gender**

Both

**Phase**

3

**Groups that have been masked***No information***Sample size**Target sample size: **40****Randomization (investigator's opinion)**

Randomized

**Randomization description**

All the arrangements of the two groups will be drawn in pairs in quadruple blocks and each block will be numbered from 1 to the end. Using a table of random numbers, the blocks are selected in order and based on the arrangement of that block, patients will be divided into one of two groups according to the order of admission.

**Blinding (investigator's opinion)**

Not blinded

**Blinding description****Placebo**

Not used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

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**Street address**

Vice-chancellery for research, Isfahan University of Medical Sciences, Hezar-Jerib Avenue

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8174673461

**Approval date**

2021-05-17, 1400/02/27

**Ethics committee reference number**

IR.MUI.RESEARCH.REC.1400.069

**Health conditions studied****1****Description of health condition studied**

Acne vulgaris

**ICD-10 code**

Acne vulga

**ICD-10 code description**

L70.0

**Primary outcomes****1****Description**

Percentage change in mGAGS scale at the end of the intervention

**Timepoint**

Before the intervention, 28 days after the start of intervention

**Method of measurement**

Visio Face - Camera

**2****Description**

Change the number of lesions at the end of the intervention

**Timepoint**

Before the intervention, 28 days after the start of intervention

**Method of measurement**

Visio Face - Camera

**3****Description**

Change of the number of lesions based on the type of lesion at the end of the intervention

**Timepoint**

Before the intervention, 28 days after the start of intervention

**Method of measurement**

Visio Face - Camera

**Secondary outcomes****1****Description**

Number of people with complete recovery at the end of the intervention

**Timepoint**

Before the intervention, 28 days after the start of intervention

**Method of measurement**

Observation

**2****Description**

Time required for complete recovery

**Timepoint**

Before the intervention, 28 days after the start of intervention

**Method of measurement**

Observation

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

Intervention group: 5% Berberis integerrima extract and 1% thyme essential oil in 70% ethanol topical solution, made by Isfahan University of Medical Science, School of Pharmacy, for 28 days

**Category**

Treatment - Drugs

**2****Description**

Control group: clindamycin 1% in 70% ethanol topical solution, made by Isfahan University of Medical Science, School of Pharmacy, for 28 days

**Category**

Treatment - Drugs

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

Isfahan Dermatology and Leishmaniasis Research Center Clinic

**Full name of responsible person**

Rasool Soltani

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Khorram Ave. Skin and Leishmaniasis Research Center

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

Esfahan University of Medical Sciences

**Full name of responsible person**

Shaghayegh Haghjoo Javanmard

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

No

**Title of funding source**

Isfahan 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**

Esfahan University of Medical Sciences

**Full name of responsible person**

Rasool Soltani

**Position**

Associated Professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Medical Pharmacy

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## Person responsible for scientific inquiries

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## Person responsible for updating data

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## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**

No - There is not a plan to make this available

**Justification/reason for indecision/not sharing IPD**

There is no necessity.

**Study Protocol**

No - There is not a plan to make this available

**Statistical Analysis Plan**

No - There is not a plan to make this available

**Informed Consent Form**

No - There is not a plan to make this available

**Clinical Study Report**

No - There is not a plan to make this available

**Analytic Code**

No - There is not a plan to make this available

**Data Dictionary**

No - There is not a plan to make this available