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)

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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
کمیته اخلاق دانشگاه علوم پزشکی اصفهان
Street address
Vice-chancellery for research, Isfahan University of Medical Sciences, Hezar-Jerib Avenue
City
Isfahan
Province
Isfehan
Postal code
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
Street address
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
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research@mui.ac.ir
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 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