Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Comparison of the effect of Aloe Vera gel and placebo on the severity of lesions in patients with acne vulgaris

Protocol summary

Study aim
Determine the effect of aloe vera gel on the severity of lesions in acne patients
Design
Controlled clinical trial with a parallel group design
Settings and conduct
This study is done in the skin clinic. Samples will be selected from patients with acne vulgaris.
Participants/Inclusion and exclusion criteria
The inclusion criteria included:Age between 18 and 40 years and satisfaction participate in the study. Exclusion criteria included: discontinuation from the study and allergic to Aloe Vera gel.
Intervention groups
Group 1 (intervention): topical application of Aloe vera plant gel, once a week for two weeks Group 2 (placebo): Topical use of distilled water, once a week for two weeks
Main outcome variables
Severity of acne lesions

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20130731014229N9**
Registration date: **2019-04-08, 1398/01/19**
Registration timing: **registered_while_recruiting**

Last update: **2019-04-08, 1398/01/19**
Update count: **0**
Registration date
2019-04-08, 1398/01/19

Registrant information
Name
Hadi Jafari manesh
Name of organization / entity
Arak University of Medical Science
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2019-03-11, 1397/12/20
Expected recruitment end date
2019-06-21, 1398/03/31
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison of the effect of Aloe Vera gel and placebo on the severity of lesions in patients with acne vulgaris

Public title
The effect of Aloe vera gel on the severity of acne lesions
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Age of 15 to 40 years Aloe Vera gel insensitivity
Exclusion criteria:
Do not use Aloe Vera gel more than once Cancellation of participation in the study Pregnancy and lactation
Age
From **15 years** old to **40 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Participant
- Data analyser

Sample size
Target sample size: **70**
Actual sample size reached: **70**
Randomization (investigator's opinion)
Randomized
Randomization description
The samples are randomly assigned to quadruple blocks A, A, B, B in random groups.
Blinding (investigator's opinion)
Double blinded
Blinding description
Participants and data analyzer do not know which groups are located. The samples in the intervention and control group did not know whether they received the placebo or the main drug. The statistician will receive questionnaires as anonymously and in form A and B, and he does not know which are intervention and control group.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
کمیته اخلاق دانشگاه علوم پزشکی اراک
Street address
Basij Sq.
City
Arak
Province
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Postal code
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Approval date
2019-02-24, 1397/12/05
Ethics committee reference number
IR.ARAKMU.REC.1397.378

Health conditions studied

1

Description of health condition studied
Acne vulgaris
ICD-10 code
L70.0
ICD-10 code description
Acne vulgaris

Primary outcomes

1

Description
total lesion count
Timepoint
Measuring the severity of acne lesions at the beginning of the study (before the intervention) and 7, 14 days after the start of use of Aloe Vera gel
Method of measurement
Global Acne Grading system or GAGS

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: In the intervention group, in addition to the medications prescribed by the doctor, topical application of 5 mm of natural aloe vera plant gel for 15 days a day
Category
Treatment - Drugs

2

Description
Control group: For the control group, distilled water is used as the drug
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Dermatology Clinic Dr. Mirnezami
Full name of responsible person
Hadi Jafarianesh
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Abasabad Ave.
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Arak University of Medical Sciences

Full name of responsible person
Mohammad Arjomandzadegan

Street address
Deputy of Research and Technology, Arak University of Medical Sciences, Basij Square, Sardasht, Arak, Iran

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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
Arak 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
Arak University of Medical Sciences

Full name of responsible person
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Position
Faculty

Latest degree
Master

Other areas of specialty/work
Nursery

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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