Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

The effect of topical herbal formulation containing of aloe vera gel,licorice, pomegranate and zataria extract on mild to moderate acne

Protocol summary

Study aim
The aim of this study is to determine the Effectiveness of Licorice, Pomegranate, Aloe vera and Zataria topical formulation on reducing mild to moderate acne symptoms.

Design
Two arm parallel double blinded randomised clinical trial phase 2-3 with 2 groups; Control group and Intervention group.

Settings and conduct
All patients referred to Alzahra hospital of Isfahan, Iran, who have inclusion criteria were assigned randomly in one of the treatment methods for 8 weeks. These patients randomly receive a package containing a herbal formulation or clindamycin .Unique codes, which is generated by the software, will be used on the drug boxes. During the research, the randomization list is held by the statistic consultant, and the participants, the project implementer and all those who participate in the measurement of the indicators will not be aware of the assigned groups.then response of treatment will be evaluated at week 4, 8, 12.

Participants/Inclusion and exclusion criteria
Inclusion criteria: patients with mild to moderate acne, defined as global acne grading system (GAGS) scale,patients who have not used topical anti acne drugs in the recent month,patients who have not used oral anti acne drugs in past 2 months Exclusion criteria:pregnancy,had a skin disease,were known to be allergic or sensitive to any of the study medications,lactating.

Intervention groups
"Control group": Patients who receive topical Gel of clindamycin 1% Najo after washing with antibacterial soap 3times in day for two months "Intervention group": Patients who receive topical herbal formulation made in ahvaz pharmacy school containing extract of Licorice , Pomegranate, Zataria and Aloe vera gel after washing with antibacterial soap 3 times in day for two months

Main outcome variables
Total lesion count and acne severity index

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20181026041466N1**
Registration date: **2018-12-12, 1397/09/21**
Registration timing: **registered_while_recruiting**

Last update: **2018-12-12, 1397/09/21**
Update count: **0**

Registration date
2018-12-12, 1397/09/21

Registrant information

Name
Ali Aghaei

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 61 3333 8149

Email address
ali.aghaei110@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-11-11, 1397/08/20

Expected recruitment end date
2019-02-09, 1397/11/20

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The effect of topical herbal formulation containing of aloe vera gel,licorice, pomegranate and zataria extract on mild to moderate acne

Public title
The effect of a topical herbal formulation on mild to moderate acne

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
patients with mild to moderate acne, defined as global acne grading system (GAGS) scale patients who have not used topical anti acne drugs in the recent month patients who have not used oral anti acne drugs in past 2 months

Exclusion criteria:
pregnancy had a skin disease were known to be allergic or sensitive to any of the study medications lactating

Age
From **12 years** old to **55 years** old

Gender
Both

Phase
2-3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **66**

Randomization (investigator's opinion)
Randomized

Randomization description
For randomization, the permuted block randomization will be used with quadruple blocks. blocks will be produced by using the online site (www.sealedenvelope.com)

Blinding (investigator's opinion)
Double blinded

Blinding description
Unique codes, which is generated by the software, will be used on the drug boxes. By entering each individual into the study based on the produced sequence, the drug box in which the code is registered, will be assigned to the individual. During the research, the randomization list is held by the statistic consultant, and the participants, the project implementer and all those who participate in the measurement of the indicators will not be aware of the assigned groups

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Ahvaz Jundishapur University of Medical Sciences

Street address
Ahvaz Jundishapur University of Medical Sciences, Golestan Road

City
Ahvaz

Province
Khouzestan

Postal code
-61357-15794

Approval date
2018-10-20, 1397/07/28

Ethics committee reference number
IR.AJUMS.REC.1397.534

Health conditions studied

1

Description of health condition studied
Acne

ICD-10 code
L70

ICD-10 code description
Acne

Primary outcomes

1

Description
Total lesion count

Timepoint
Before intervention, 4th and 8th weeks after start of intervention and 4 weeks after end of intervention.

Method of measurement
counting the comedones, papules and pustules number.

Secondary outcomes

1

Description
acne severity index

Timepoint
Before intervention, 4th and 8th weeks after start of intervention and 4 weeks after end of intervention.

Method of measurement
Counting lesions based on Acne Severity Index

Intervention groups

1

Description
Control group: topical use Clindamycin 1% Najo after washing with antibacterial soap 3times in day for two months
Category
Treatment - Drugs

2

Description
Intervention group: topical use herbal formulation made in ahvaz pharmacy school containing extract of Licorice , Pomegranate, Zataria and Aloe vera gel after washing with antibacterial soap 3 times in day for two months
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Alzahra Hospital
Full name of responsible person
Masoudali Karami
Street address
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Ahvaz University of Medical Sciences
Full name of responsible person
Dr.Mohammad Badavi
Street address
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6135733184
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Email
Badavim@yahoo.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Ahvaz 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
Ahvaz University of Medical Sciences
Full name of responsible person
Ali Aghaei
Position
Student
Latest degree
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

Only a part of the data will be shared

When the data will become available and for how long

The access period will be 6 months after the publication of the results

To whom data/document is available

Six months after the publication of this study papers, the obtained data will be available to the applicant researchers for further analysis

Under which criteria data/document could be used

Six months after the publication of this study papers, the obtained data will be available to the applicant researchers for further analysis

From where data/document is obtainable

Applicants can be contacted with corresponding author by e-mail

What processes are involved for a request to access data/document

Applicants will be able to access the obtained data from current study by sending an email to the corresponding author up to one month

Comments