

Clinical Trial Protocol

Iranian Registry of Clinical Trials

05 Jul 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 3 times 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.ghaei110@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

Khuzestan

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

Alzahra Hospital, Soffeh Blvd

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Isfahan

Province

Isfahan

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8179604891

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Alzahra@mui.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

Dr.Mohammad Badavi

Street address

Ahvaz Jundishapur University of medical Sciences,
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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

A Level or less

Other areas of specialty/work

Medical Pharmacy

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Person responsible for scientific inquiries

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Associate professor

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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