Clinical Trial Protocol
Iranian Registry of Clinical Trials

11 Sep 2026

Comparison of the Effectiveness of a herbal anti acne gel with clindamaycin gel in patients with mild to moderate acne

Protocol summary

Study aim

The aim of this study is to determine the Effectiveness of topical herbal 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 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 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: **IRCT20181026041466N3**
Registration date: **2020-08-31, 1399/06/10**
Registration timing: **registered_while_recruiting**

Last update: **2020-08-31, 1399/06/10**
Update count: **0**

Registration date

2020-08-31, 1399/06/10

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

2020-08-21, 1399/05/31

Expected recruitment end date

2021-02-18, 1399/11/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the Effectiveness of a herbal anti acne gel with clindamaycin gel in patients with mild to moderate acne

Public title
preparation and clinical trial Of herbal anti acne gel in comparison with clindamaycin gel
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
patients with mild to moderate acne, defined as global acne grading system (GAGS) scale who patients who have not used topical anti acne drugs in the recent month patients have not used oral anti acne drugs in past 2 months
Exclusion criteria:
Age
From **15 years** old to **40 years** old
Gender
Both

Phase
2
Groups that have been masked

- Participant
- Care provider
- Investigator
- Data analyser

Sample size
Target sample size: **60**
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
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
2020-07-24, 1399/05/03
Ethics committee reference number
IR.AJUMS.REC.1399.368

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.

2

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

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: topical use herbal formulation made in ahvaz pharmacy school after washing with antibacterial soap 3 times in day for two months
Category

Treatment - Drugs

2

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

Recruitment centers

1

Recruitment center
Name of recruitment center
مطب خصوصی
Full name of responsible person
فاروق آقایی
Street address
koote abdollah
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Ahvaz
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6135733184
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ali.aghaei110@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Rayka raya teb co
Full name of responsible person
ali aghaei
Street address
golestan
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ahvaz
Province
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ali.aghaei110@gmail.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Rayka raya teb co
Proportion provided by this source
100
Public or private sector
Private
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Industry

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
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Person responsible for updating data

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Position

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Latest degree

A Level or less

Other areas of specialty/work

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Email

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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