Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Comparision of Therapeutic effects of the herbal anti acne formulation (Acdine gel, Tea Tree Oil 5%) and topical clindamycin in mild acne vulgaris treatment

Protocol summary

Study aim
Compare Therapeutic Effects of Acidine Gel Formulation with 5% Tea Tree Oil and Topical Clindamycin in the Treatment of Acne Vulgaris

Design
Patients treated with Akdin gel containing 5% tea tree oil and patients treated with Clindamycin gel daily 2 times

Settings and conduct
In this study, 60 patients aged 15-30 years with mild acne vulgaris were selected from among patients referring to dermatology clinic of Sina Hospital in Tabriz. Accidentally, 30 patients of Akdin gel containing tea tree oil were 5% and 30 others Clindamycin gel will be given twice a day.

Participants/Inclusion and exclusion criteria
Inclusion criteria: 1) patients with mild acne with an average age of 30-15 years 2) Patients with up to 10 inflammatory lesions (just papules or pustules) and lack of nodules, cysts or scars 3) Not having other inflammatory diseases involving the face 4) Not having other acne exacerbatory systemic diseases, such as Cushing's syndrome, PCOS, adrenal hyperplasia, inherited immune deficiency, steroid acne and acne rash 5) Patients who have not used oral or topical anticancer drugs during the past month 6) Patient satisfaction to participate in the study Exclusion criteria: 1) Age under 15 and over 30 years 2) Pregnant and lactating women 3) Persons who are vulnerable and have mental disabilities 4) Having systemic illness or other facial skin diseases 5) Use of topical or systemic steroid 6) Use of oral or topical anti-acne medication over a recent month 7) Having seborrheic skin

Intervention groups
Patients treated with Akdin gel containing 5% tea tree oil and patients treated with Clindamycin gel daily 2 times

Main outcome variables
Reduce the number of inflammatory and non-inflammatory lesions

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20120524009844N7**
Registration date: **2019-06-25, 1398/04/04**
Registration timing: **registered_while_recruiting**

Last update: **2019-06-25, 1398/04/04**
Update count: **0**

Registration date
2019-06-25, 1398/04/04

Registrant information

Name
Mehdi Amirnia

Name of organization / entity
Tabriz University of Medical Sciences

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-09-23, 1397/07/01

Expected recruitment end date
2019-09-21, 1398/06/30

Actual recruitment start date
empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparision of Therapeutic effects of the herbal anti acne formulation (Acdine gel, Tea Tree Oil 5%) and topical clindamycin in mild acne vulgaris treatment

Public title

Therapeutic effects of the herbal anti acne formulation gel Tea Tree Oil in mild acne vulgaris treatment

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

patients with mild acne with an average age of 30-15 years Patients with up to 10 inflammatory lesions (just papules or pustules) and lack of nodules, cysts or scars Not having other inflammatory diseases involving the face Not having other acne exacerbatory systemic diseases, such as Cushing's syndrome, PCOS, adrenal hyperplasia, inherited immune deficiency, steroid acne and acne rash Patients who have not used oral or topical anticancer drugs during the past month Have Patient Satisfaction to Participate in the Study

Exclusion criteria:

Age under 15 and over 30 years Pregnant and lactating women Persons vulnerable and mentally impaired Having systemic illness or other facial skin diseases Use of topical or systemic steroids Oral or topical anti-acne medication over a recent month Having seburic skin

Age

From **15 years** old to **30 years** old

Gender

Both

Phase

3

Groups that have been masked

- Outcome assessor
- Data and Safety Monitoring Board

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomized randomization will be carried out with a simple randomization unit using the Radlist software. This allocation will be placed by a person independent of the study in the envelope and will remain hidden until the end of the study.

Blinding (investigator's opinion)

Double blinded

Blinding description

The treatment assessor and the statistical analyst will not be aware of the allocation of intervention until the end of the study.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Tabriz University of Medical Sciences

Street address

Daneshgah

City

Tabriz

Province

East Azarbaijan

Postal code

5142954481

Approval date

2016-06-16, 1395/03/27

Ethics committee reference number

IR.TBZMED.REC.1395.274

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

Reduce the number of inflammatory and non-inflammatory lesions

Timepoint

Every 7 days

Method of measurement

By Visiting and examination with doctor

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Acadin group

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Sina teaching hospital
Full name of responsible person
Dr. Mehdi Amirnia
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Full name of responsible person
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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
Tabriz 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
Tabriz University of Medical Sciences
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Dr. Mehdi Amirnia
Position
professor
Latest degree
Specialist
Other areas of specialty/work
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Full name of responsible person

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Latest degree

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Email

Roya.mirhaji@gmai.lcom

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

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

Not applicable

Title and more details about the data/document

En All data will be shared after being unidentified.

When the data will become available and for how long

At any time

To whom data/document is available

It will be free for everyone.

Under which criteria data/document could be used

There are no special conditions

From where data/document is obtainable

Email: mehamir46@gmail.com Dr Mehdi Amirnia 09143113577 Dermatology Department - Sina Hospital- Azadi Street- Tabriz

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

The Request will be checked, then data will be sent by Email in 1 month

Comments