

Clinical Trial Protocol

Iranian Registry of Clinical Trials

14 Jun 2026

Effect of Chamomile Extract Gel on Acne Vulgaris Recovery in Patients Referred to Dermatology Department of Sina Hospital in Tabriz and Comparison with Clindamycin gel

Protocol summary

Study aim

The overall goal of this project was to find out the effect of chamomile flower extract on inflammatory acne vulgaris formulated in gel formulation to determine the rate at which it can cure or prevent acne.

Design

In this randomized clinical trial study, 44 patients with mild to moderate acne vulgaris who were included in the study were divided into two parallel control groups (group 1: clindamycin gel 1%) and intervention group (group 2: clindamycin gel combination 1% and Topical chamomile gel (2%), in which each group consisted of 22 individuals, was studied.

Settings and conduct

After preparing the whole chamomile extract and formulating it as a gel, the design was carried out at a dermatologist's clinic in Sina Hospital under the supervision of a specialist physician. Patients were informed of their satisfaction with the explanations given in this regard. They completed the questionnaire. Patients participating in the study were evaluated weekly and their information was recorded in the relevant questionnaire.

Participants/Inclusion and exclusion criteria

In this randomized clinical trial study, 44 patients with mild to moderate acne vulgaris who had inclusion criteria Entry requirements: Patients with mild to moderate acne Patients who have at least 2 inflammatory lesions (papules and pustules). • Not having any skin diseases involved, such as allergic, etc. • Patients who do not need systemic antibiotics. Exclusion criteria: Patients with severe acne • Having other skin diseases that affect the study • Patient dissatisfaction • In case of drug allergy

Intervention groups

The effect of formulated gel of chamomile extract on acne vulgaris in two groups is as follows: Control group

(group 1: clindamycin gel 1%) Intervention group (Group 2: clindamycin gel 1% and chamomile gel 2%)

Main outcome variables

Number of Papules; Number of Postures; Number of Comedones

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190526043718N1**

Registration date: **2019-08-29, 1398/06/07**

Registration timing: **retrospective**

Last update: **2019-08-29, 1398/06/07**

Update count: **0**

Registration date

2019-08-29, 1398/06/07

Registrant information

Name

Mahsa Dolatpanah

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 41 3337 2250

Email address

mahsa.d.panah@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-10-12, 1397/07/20

Expected recruitment end date

2019-04-17, 1398/01/28

Actual recruitment start date

2018-11-02, 1397/08/11

Actual recruitment end date

2019-04-25, 1398/02/05

Trial completion date

2019-04-25, 1398/02/05

Scientific title

Effect of Chamomile Extract Gel on Acne Vulgaris Recovery in Patients Referred to Dermatology Department of Sina Hospital in Tabriz and Comparison with Clindamycin gel

Public title

Effect of chamomile gel on acne

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

All patients with mild to moderate acne All patients with acne who do not need systemic medication

Exclusion criteria:

People who are allergic to herbal ingredients Those with severe acne People who need antibiotics or other medications

Age

No age limit

Gender

Both

Phase

3

Groups that have been masked*No information***Sample size**Target sample size: **44**Actual sample size reached: **44****Randomization (investigator's opinion)**

Not randomized

Randomization description**Blinding (investigator's opinion)**

Not blinded

Blinding description**Placebo**

Not 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

No. 3, Mokhaberat Alley, Fifth Alley, Shahid Chamran

Square

City

Sarab

Province

East Azarbaijan

Postal code

5471954833

Approval date

2018-09-25, 1397/07/03

Ethics committee reference number

IR.TBZMED.REC.1397.526

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**

The mean number of papules, pustules and comedones and the total number of inflammatory lesions and comparing them in control and intervention groups

Timepoint

Measurement of Papules, Pustules and Commons at baseline (before intervention) and 21, 14, 7 days after drug administration in both groups

Method of measurement

View and count the number of acne

Secondary outcomes**1****Description**

Percentage of complete recovery after treatment in both groups

Timepoint

7,14,21 days after intervention (baseline)

Method of measurement

Observe and measure the number of acne

Intervention groups**1****Description**

Intervention group: 22 patients treated with gel of chamomile plant extract 2%(twice daily) for 21 days were treated topically on the lesion only.

Category

Treatment - Drugs

2

Description

Control group: 22 patients treated with topical clindamycin gel 1% (once daily) for 21 days were treated with topical only on the lesion.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Sina Hospita

Full name of responsible person

Hamide Azimi

Street address

Sina Hospital, Azadi Ave., between Shahid Montazeri and Hafez intersection, Tabriz

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research-vice@tbzmed.ac.ir

Web page address

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Dr. Abolghasem Jouyban

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Faculty of Pharmacy, Attar Neyshaburi Street, Neyayesh Blvd

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

No

Title of funding source

Vice chancellor for research, 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

Full name of responsible person

Yousef Javadzade

Position

professor

Latest degree

Ph.D.

Other areas of specialty/work

Medical Pharmacy

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

No more information

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

No - There is not a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Not applicable