

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Evaluation of the effect of topical formulation prepared from hydroalcoholic extract of *Arctium Lappa*'s root in the treatment of mild and moderate Acne Vulgaris

Protocol summary

Study aim

Evaluation of the efficacy of topical formulation of *Arctium Lappa* extract in the treatment of acne vulgaris

Design

Patients undergo a phase 3 trial with the help of a list provided by randomization.com, divided into intervention and control groups and receiving treatment in parallel for each group.

Settings and conduct

Patients are examined by a physician after signing an informed consent form by attending the dermatology clinic of Imam Reza Hospital and receive the appropriate treatment randomly.

Participants/Inclusion and exclusion criteria

Women and men 12 to 30 years with acne vulgaris and no other systemic or skin diseases

Intervention groups

Patients were randomly divided into intervention and control groups, the intervention group using topical tretinoin and *Arctium Lappa* each day on the face; the control group used topical tretinoin twice daily on the face. Finally, the rate of improvement in skin lesions in these two groups was compared after three months of drug administration.

Main outcome variables

improvement of acne vulgaris lesions

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20191111045408N1**

Registration date: **2019-11-24, 1398/09/03**

Registration timing: **prospective**

Last update: **2019-11-24, 1398/09/03**

Update count: **0**

Registration date

2019-11-24, 1398/09/03

Registrant information

Name

Amirreza Entezari

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-04-13, 1399/01/25

Expected recruitment end date

2021-01-14, 1399/10/25

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effect of topical formulation prepared from hydroalcoholic extract of *Arctium Lappa*'s root in the treatment of mild and moderate Acne Vulgaris

Public title

Evaluation of the effect of formulation *Arctium Lappa* in the treatment of Mild-to-moderate Acne

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Women and men aged 12-30 years with mild to moderate acne vulgaris Have signed the informed consent form

Exclusion criteria:

Pregnant or breastfeeding or planning to become pregnant Have a history of sensitivity to the components of the formulations used in the study Other skin diseases such as eczema that make it difficult to evaluate the response to treatment Have uncontrolled systemic disease They have Acne Conglobata Not taking the following drugs before starting the plan (topical anti-acne drugs for two weeks, oral antibiotics for one month, 12 weeks hormone therapy and 6 months oral retinoids).

Age

From **12 years** old to **30 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Investigator
- Outcome assessor

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

Use simple randomization with the help of a listing provided by randomization.com

Blinding (investigator's opinion)

Triple blinded

Blinding description

In this study, 100 patients with mild-to-moderate acne vulgaris referred to the special clinic of Ghaem Hospital, Mashhad, who met the inclusion criteria, will be enrolled after obtaining informed consent. Patients in groups A and B receive tretinoin gel, and then patients are randomly assigned to group A or B and receive placebo gel (B) or Arctium Lappa's gel (A) with tretinoin gel. Patients in groups C and D also receive tretinoin cream, which in turn will receive cream containing Arctium Lappa (C) or placebo (D). The first 50 patients will be divided between groups A and B and the next 50 patients will be divided between groups C and D. The placebo and herbal formulations will be delivered in the same package to the patients, which will have a very similar appearance and will be prepared by an individual other than the treating physician and the evaluating pharmacy student, distinguished only by the letters A, B, C or D, and The physician, pharmacy student, patient, and analyzer will remain unaware of the formulation until the work is completed.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Mashhad University of Medical Sciences

Street address

Mashhad, Daneshgah Ave, Central Organization of Mashhad University of Medical Sciences

City

Mashhad

Province

Razavi Khorasan

Postal code

1394491388

Approval date

2019-09-21, 1398/06/30

Ethics committee reference number

IR.MUMS.REC.1398.180

Health conditions studied

1

Description of health condition studied

Acne Vulgaris

ICD-10 code

L70.0

ICD-10 code description

Acne vulgaris (or simply acne) is a long-term skin disease that occurs when hair follicles become clogged with dead skin cells and oil from the skin. Acne is characterized by areas of blackheads, whiteheads, pimples, and greasy skin, and may result in sca

Primary outcomes

1

Description

Acne Complication

Timepoint

One month after intervention, two months after intervention, three months after intervention

Method of measurement

Based on acne lesion counting

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Topical tretinoin formulation and Arctium Lappa topical formulation are applied once daily for three months on face skin.

Category
Treatment - Drugs

2

Description
Control group: Topical application of tretinoin twice daily for three months

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Imam Reza Hospital

Full name of responsible person
Sepideh Elyasi

Street address
Imam Reza Square, Imam Reza Hospital

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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
Mashhad 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
Mashhad University of Medical Sciences

Full name of responsible person
Amirreza Entezari

Position
Pharmacy Student

Latest degree
Medical doctor

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)

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

The information listed will be published in the form of an article.

When the data will become available and for how long

The article will be available through Infinite Journal.

To whom data/document is available

Anyone who needs them can access.

Under which criteria data/document could be used

The data not published in this article will be provided in coordination with all project partners and research assistants of Mashhad University of Medical Sciences.

From where data/document is obtainable

Email the person in charge

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

The consent of all research associates of Mashhad University of Medical Sciences should be obtained.

Comments