

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

18 Jul 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)

###### Phone

+98 51 4333 4374

###### Email address

entezariar941@mums.ac.ir

##### 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**  
Mashhad University of Medical Sciences

**Full name of responsible person**  
Mohsen Tafaqodi

**Street address**  
VakilAbad Blvd, School of Pharmacy

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17871 91886

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hassanzadehmm1@mums.ac.ir

**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 scientific inquiries

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## Person responsible for updating data

### Contact

**Name of organization / entity**  
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Student of Pharmacy  
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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