

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

02 Jun 2026

### The effect of gel containing of aloe vera gel and licorice extract on mild to moderate acne vulgaris

#### Protocol summary

##### Summary

This study is a randomized, double-blind, control trial on patients > 12 years old Who referred to dermatology clinic or office with mild to moderate acne vulgaris. If the Volunteers taking the medication for acne in the past 2 months or allergy to medicine used in the study Can not be included in the study. At first randomly divided into two groups containing aloe vera and licorice gel or clindamycin 1% gel. Both drugs are consumed locally bedtime and after washing with antibacterial soap. The duration of study 8 weeks and Volunteers 4 times visit. Baseline, the end of the first week, the fourth week and eighth weeks. In addition to the grading acne at each visit, the total lesion count (TLC) and acne severity index (ASI) per person calculated and compared.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2016021412438N17**

Registration date: **2016-02-16, 1394/11/27**

Registration timing: **prospective**

Last update:

Update count: **0**

##### Registration date

2016-02-16, 1394/11/27

##### Registrant information

##### Name

Mohsen Taghizadeh

##### Name of organization / entity

Kashan University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 36 1555 0021

##### Email address

taghizadeh\_m@kaums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Barij Research Center of Medicinal Plants

##### Expected recruitment start date

2016-04-03, 1395/01/15

##### Expected recruitment end date

2016-09-22, 1395/07/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The effect of gel containing of aloe vera gel and licorice extract on mild to moderate acne vulgaris

##### Public title

The effect of gel containing of aloe vera and licorice on acne vulgaris

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

Inclusion criteria: patients with mild to moderate acne, defined as GAGS scale, who were not satisfied with their previous acne therapies participated in the study after giving written informed consent Exclusion criteria: pregnancy or lactation; had received topical anti acne therapy two months before or during the study or any systemic therapy with antibiotics; had a skin disease that might interfere with the diagnosis or evaluation of their hyper pigmentation; were known to be allergic or sensitive to any of the study medications or their components

##### Age

From **12 years** old to **139 years** old

**Gender**

Both

**Phase**

2-3

**Groups that have been masked***No information***Sample size**Target sample size: **60****Randomization (investigator's opinion)**

Randomized

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

Double blinded

**Blinding description****Placebo**

Not used

**Assignment**

Parallel

**Other design features**

Randomized based on table of random numbers

**Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Ethics committee of Kashan University of Medical Sciences

**Street address**

Kashan University Of Medical Sciences, Kashan

**City**

Kashan

**Postal code****Approval date**

2016-02-03, 1394/11/14

**Ethics committee reference number**

IR.KAUMS.REC.1394.149

**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**

acne grading

**Timepoint**

Baseline and End-of-trial

**Method of measurement**

Global Acne Grading System(GAGS)

**2****Description**

acne severity

**Timepoint**

Baseline, the end of the first and fourth weeks, end of the study

**Method of measurement**

acne severity index(ASI)

**3****Description**

total lesion count

**Timepoint**

Baseline, the end of the first and fourth weeks, end of the study

**Method of measurement**

total lesion count( TLC)

**Secondary outcomes**

empty

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

intervention: topical use herbal gel after washing with antibacterial soap every night at bedtime for two months

**Category**

Treatment - Drugs

**2****Description**

control: topical use Clindamycin after washing with antibacterial soap every night at bedtime for two months

**Category**

Treatment - Drugs

**Recruitment centers****1****Recruitment center****Name of recruitment center**

Dr R.Talaee office

**Full name of responsible person**

Dr Rezvan Talaee

**Street address****City**

Kashan

**2****Recruitment center****Name of recruitment center**

Shahid Beheshti hospital dermatology clinic  
**Full name of responsible person**  
Dr Rezvan Talaee  
**Street address**  
**City**  
Kashan

*empty*  
**Category of foreign source of funding**  
*empty*  
**Country of origin**  
**Type of organization providing the funding**  
*empty*

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**  
Barij Research Center of Medicinal Herbs  
**Full name of responsible person**  
Miss L.Hejazi  
**Street address**  
Kashan Mashhad Ardehal Road, KM44  
**City**  
Kashan

#### Grant name

#### Grant code / Reference number

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

Yes

#### Title of funding source

Barij Research Center of Medicinal Herbs

#### Proportion provided by this source

#### Public or private sector

*empty*

#### Domestic or foreign origin

*empty*

#### Category of foreign source of funding

*empty*

#### Country of origin

#### Type of organization providing the funding

*empty*

### 2

#### Sponsor

**Name of organization / entity**  
Vice chancellor for research of Kashan University of Medical Science  
**Full name of responsible person**  
Dr Gholam Ali Hamidi  
**Street address**  
Kashan university of Medical Science, Kashan  
**City**  
Kashan

#### Grant name

#### Grant code / Reference number

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

Yes

#### Title of funding source

Vice chancellor for research of Kashan University of Medical Science

#### Proportion provided by this source

#### Public or private sector

*empty*

#### Domestic or foreign origin

## Person responsible for general inquiries

#### Contact

##### Name of organization / entity

Kashan University of Medical Sciences

##### Full name of responsible person

Dr.M.Taghizadeh

##### Position

PHD

##### Other areas of specialty/work

##### Street address

Kashan University Of Medical Sciences, Kashan

##### City

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##### Postal code

##### Phone

+98 31 5554 0021

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mohsenta44@yahoo.com

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## Person responsible for scientific inquiries

#### Contact

##### Name of organization / entity

Kashan University of Medical Sciences

##### Full name of responsible person

Dr rezvan talaie

##### Position

Dermatologist

##### Other areas of specialty/work

##### Street address

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## Person responsible for updating data

#### Contact

##### Name of organization / entity

Barij Research Center of Medicinal Herbs

##### Full name of responsible person

M.Mahlouji

##### Position

Clinical Expert

##### Other areas of specialty/work

**Street address**

Km. 44 of Kashan - Delijan Rd, Mashhad-e- Ardehal  
Kashan

**City**

Kashan

**Postal code****Phone**

00

**Fax****Email**

mahnaz.mahlouji@yahoo.com

**Web page address****Sharing plan****Deidentified Individual Participant Data Set (IPD)**

*empty*

**Study Protocol**

*empty*

**Statistical Analysis Plan**

*empty*

**Informed Consent Form**

*empty*

**Clinical Study Report**

*empty*

**Analytic Code**

*empty*

**Data Dictionary**

*empty*