

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Comparison of the efficacy of oral *Trigonella foenum-graecum* seed extract and oral azithromycin in the severity of acne vulgaris; a randomized controlled clinical trial

Protocol summary

Summary

The study conduct to determine the effect of *Trigonella foenum-graecum* on acne vulgaris. 20 patients with clinical diagnosis of acne vulgaris will refer to the dermatology department of the shahid faghihi hospital. Patients in the study must have mild to moderate acne (GAGS: 1-30) and aged 12 to 30 years old. Participants either will receive two oral capsules each one containing 500 mg hydroalcoholic extract of *Trigonella foenum-graecum* (fenugreek) seed or two azithromycin capsule (each one 125mg azithromycin) daily for two months. The azithromycin capsules will be similar in color, shape, size, and package to the fenugreek capsules. We will evaluate patients 30 and 60 days after starting of the trial to reassess clinical changes and ask them about any potential side effects (Such as allergic reactions, bloating, transient diarrhea, severe weight loss, hypoglycemia, dizziness and cold sweats).

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015091123978N1**
Registration date: **2017-11-05, 1396/08/14**
Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2017-11-05, 1396/08/14

Registrant information

Name

Ali Mohammadi

Name of organization / entity

Shiraz University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 71 3230 5410

Email address

mohamad_al@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Shiraz University of Medical Sciences

Expected recruitment start date

2015-07-23, 1394/05/01

Expected recruitment end date

2017-05-22, 1396/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the efficacy of oral *Trigonella foenum-graecum* seed extract and oral azithromycin in the severity of acne vulgaris; a randomized controlled clinical trial

Public title

Effect of Fenugreek in treatment of Acne Vulgaris

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: age 12 to 30 years; GAGS score between 1 and 30; signature consent form. Exclusion criteria: previous consumption of oral acne controller medications, such as antibiotics, isotretinoin, oral contraceptive pills; administration of drugs that caused acne such as testosterone, progesterone, steroids,

lithium, phenytoin, and isoniazid; patients with symptoms of endocrine disorders especially hyperandrogenism, including polycystic ovarian syndrome (oligomenorrhea, polycystic ovaries, hirsutism), Cushing syndrome (rapid weight gain, buffalo hump, moon face, excess sweating, purple or red striae on the body and hirsutism), CAH, androgen-secreting tumors, and acromegaly; severe skin problem; women who were pregnant or lactating.

Age

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

Gender

Both

Phase

0

Groups that have been masked

No information

Sample size

Target sample size: **20**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Triple blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Shiraz University of Medical Sciences

Street address

Shiraz University of Medical Sciences, Zand street

City

Shiraz

Postal code

71345-1583

Approval date

2014-09-02, 1393/06/11

Ethics committee reference number

CT-P-9362-6852

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

Severity of skin lesions

Timepoint

At baseline, 30 and 60 days after intervention

Method of measurement

Global Acne Grading System (GAGS)

Secondary outcomes

1

Description

changes in lesions count (total, inflammatory, non-inflammatory and regional)

Timepoint

At baseline, 30 and 60 days after intervention

Method of measurement

visual counting

Intervention groups

1

Description

Intervention group, in addition to diet and hygienic recommendations, use capsules containing fenugreek hydro alcoholic extract 1g / d for 2 months.

Category

Treatment - Drugs

2

Description

Control group, in addition to diet and hygienic recommendations, use Azithromycin capsules 250mg/d for 2 months.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Faghihi Hospital

Full name of responsible person

Mojdeh Sepaskhah

Street address

Zand street

City

Shiraz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Dr. Seyed Basir Hashemi

Street address

Karim Khan Zand Street, Shiraz University of Medical Sciences

City

Shiraz

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Shiraz University of Medical Sciences

Proportion provided by this source

100

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

Person responsible for general inquiries

Contact

Name of organization / entity

Shiraz university of medical science

Full name of responsible person

Ali Mohammadi

Position

Medical Student

Other areas of specialty/work

Street address

Zand street, School of Medicine

City

Shiraz

Postal code

Phone

+98 917 736 9270

Fax

Email

dr.mohammadi71@gmail.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Mojdeh Sepaskhah

Position

Assistant Professor of Dermatology

Other areas of specialty/work

Street address

Karim Khan Street, Faghighi Hospital, Molecular Dermatology research center

City

Shiraz

Postal code

Phone

+98 71 3212 5592

Fax

Email

Sepaskhah_m@yahoo.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Amir Hossein Babaei

Position

Medical Student

Other areas of specialty/work

Street address

Zand street, School of Medicine

City

Shiraz

Postal code

Phone

+98 917 739 5073

Fax

Email

babaei93@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