Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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

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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 ot 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 hyperandrogegism, 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
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Karim khan zand street, Shiraz University of Medical Sciences
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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
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

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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