Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

The effect of cream containing vitex agnus castus extract and foeniculum vulgare essential oil on mild and moderate hirsutism symptoms

Protocol summary

Summary

This clinical trial is a randomized , double-blind , parallel, placebo-controlled study on 50 patients 15 to 35 years old with mild to moderate hirsutism on the chin, upper lip, and the2 sides face that in the past 6 months cosmetic or pharmaceutical treatment for hirsutism are not received , and other hormonal disorders will be implemented .patients devided 2 groups that receive topical herbal cream containing Vitex and fennel or placebo for 2 times in day for 6 months randomly. Inclusion criteria is based on the Ferriman and Gallway score. Hair diameter, hair growth rate, and evaluation of individual improvement will be measured monthly.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014042812438N7**
Registration date: **2014-07-04, 1393/04/13**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2014-07-04, 1393/04/13

Registrant information

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Name of organization / entity
Kashan University of Medical Sciences

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Recruitment status
Recruitment complete

Funding source
Barij research center of medicinal herbs

Expected recruitment start date
2014-06-22, 1393/04/01

Expected recruitment end date
2016-06-22, 1395/04/02

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The effect of cream containing vitex agnus castus extract and foeniculum vulgare essential oil on mild and moderate hirsutism symptoms

Public title
The effect of cream contain Vitex and Fennel on hirsutism

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:15-35 years old. mild and moderate hirsutism accordig to ferriman & gallway score exclusion criteria : sever hirsutism. cosmetic or pharmaceutical treatment for hirsutism in 6 months past.pregnancy and lactation.hyperandrogenism.other hormonal disorders.

Age
From **15 years** old to **35 years** old

Gender
Female

Phase
1-2

Groups that have been masked
No information

Sample size

Target sample size: **50**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Double blinded
Blinding description
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Kashan University of Medical Sciences
Street address
Kashan University Of Medical Sciences, Kashan
City
Kashan
Postal code
Approval date
2014-06-17, 1393/03/27
Ethics committee reference number
1354/1/5/29/پ

Health conditions studied

1

Description of health condition studied
Hirsutism
ICD-10 code
L68.0
ICD-10 code description
Hirsutism

Primary outcomes

1

Description
hair diameter
Timepoint
monthly until end of study
Method of measurement
micrometer

2

Description
hair growth rate
Timepoint
monthly until end of study
Method of measurement
shave interval

3

Description
self assesment
Timepoint
monthly until end of study
Method of measurement
VAS

Secondary outcomes

1

Description
grade of hirsutism
Timepoint
monthly until end of study
Method of measurement
ferriman and gallway

Intervention groups

1

Description
intervention group:routin treatment+ topical herbal cream 2 times in day.until 6 months
Category
Treatment - Drugs

2

Description
control group:routin treatment+ topical placebo cream 2 times in day.until 6 months
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Dr F.Foroozanfard office
Full name of responsible person
Dr.F.Foroozanfard
Street address
City
Kashan

2

Recruitment center
Name of recruitment center
Gynecology Clinic of Kashan University of Medical Science
Full name of responsible person
Dr. F Foroozanfard

Street address
City
Kashan

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
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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
Barij Research Center of Medicinal Herbs
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
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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