

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 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 the 2 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 divided 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

###### 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 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

**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**

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**

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

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taghizadeh\_m@kaums.ac.ir

**Web page address**

## Person responsible for scientific

## inquiries

### Contact

**Name of organization / entity**

Kashan University of Medical Sciences

**Full name of responsible person**

Dr. Fatemeh Foroozanfard

**Position**

OBS & GYN, IVF Fellowship, Assistant Professor

**Other areas of specialty/work**

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**Web page address**

## 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**

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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*