

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 May 2026

The Effect Of Fennel Gel (Foeniculum Vulgare) In Patient with Idiopathic Hirsutism

Protocol summary

Summary

This Randomized Double Blind Placebo controlled Clinical Trial Study will be done in Patients with Idiopathic Hirsutism who have been referred to Endocrine Clinic of Imam Khomeini Hospital of Sari. In this study Idiopathic Hirsutism was used for hirsute patients who have regular Menses and Normal serum Androgen levels. Inclusion criteria include: Female 15 – 35 years old, Mild to Moderate Hirsutism, those who haven't used an effective medications for their Hirsutism in this last six months, those who have consented to participate in the study. Exclusion criteria: Increased Level of Androgens, Irregularity of menses, Sever form of Hirsutism , Use of effective medication on Hirsutism in the last six months, Pregnancy and breast feeding . 44 Patients were randomly allocated to case and control groups. The case and control groups will receive Foeniculum Vulgare 3% and placebo gel respectively two times a Day . Hair diameter will be Measured before the start of intervention and when it is finished. The speed of hair growth, the need for removing hairs and the possible side effects will be measured monthly. At the end of third and sixth month hair diameter will be measured again and compared with the measurements before the start of the treatment.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138901213672N1**
Registration date: **2010-08-24, 1389/06/02**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2010-08-24, 1389/06/02

Registrant information

Name

Ozra Akha

Name of organization / entity

Mazandaran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 15 1326 5944

Email address

oakha@mazums.ac.ir

Recruitment status

Recruitment complete

Funding source

Mazandaran University of Medical Sciences

Expected recruitment start date

2010-04-04, 1389/01/15

Expected recruitment end date

2011-07-05, 1390/04/14

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effect Of Fennel Gel (Foeniculum Vulgare) In Patient with Idiopathic Hirsutism

Public title

The Effect Of Fennel Gel in Grow Increased (Extra) Hair

Purpose

Prevention

Inclusion/Exclusion criteria

Exclusion Criteria: 1-Increased Level of Androgen 2- Irregular Menses 3-Sever Hirsutism 4- Use of effective medication on Hirsutism in the last six months before study 5-Use of Laser in the last 6 months before study 7- Pregnancy and breastfeeding Inclusion criteria: Female

patients with Idiopathic Hirsutism that will be visited in Endocrine Clinic of Imam khomeini Hospital of Sari with regular menses and normal Androgen level

Age

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

Gender

Female

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **44**

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**

Mazandaran University of Medical Sciences

Street address

Valie Asr Street , Emam Square

City

Sari

Postal code**Approval date**

2010-03-03, 1388/12/12

Ethics committee reference number

88-146

Health conditions studied**1****Description of health condition studied**

Idiopathic Hirsutism

ICD-10 code

L68.0

ICD-10 code description

Hirsutism

Primary outcomes**1****Description**

Serum T level measurement

Timepoint

Before treatment

Method of measurement

Laboratory measurement of the hormone

2**Description**

DHEAS measurement

Timepoint

Before treatment

Method of measurement

Laboratory measurement of the hormone

3**Description**

OH-17

Timepoint

Before treatment

Method of measurement

Laboratory measurement of the hormone

Secondary outcomes**1****Description**

Rate of hair growth and its thickness

Timepoint

Before the start and after the end of treatment

Method of measurement

Questionnaire

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

Fennel gel used twice a day on face

Category

Treatment - Drugs

2**Description**

Placebo gel used twice a day on face

Category

Treatment - Drugs

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

Emam Hospital

Full name of responsible person

Street address

City

Sari

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor, Mazandaran University Of Medical Sciences

Full name of responsible person

Dr Ahmadali Enayati

Street address

Building No.2 ,Mazandaran University Of Medical Sciences,Moallem Square

City

Sari

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice Chancellor, Mazandaran 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

Mazandaran University Of Medical Sciences

Full name of responsible person

Ozra Akha

Position

Endocrinology

Other areas of specialty/work

Street address

Bilding No.2 Of University,Mallem Square

City

Sari

Postal code

Phone

+98 911 124 5156

Fax

Email

Oakha@mazums.ac.ir

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Mazandaran University Of Medical Sciences

Full name of responsible person

Dr Ozra Akha

Position

Endocrinology

Other areas of specialty/work

Street address

Mazandaran University Of Medical Sciences,Emam Square

City

Sari

Postal code

Phone

+98 911 124 5156

Fax

Email

Oakha@mazums.ac.ir

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Mazndaran University Of Medical Sciences

Full name of responsible person

Dr Ozra Akha

Position

Endocrinology

Other areas of specialty/work

Street address

City

Sari

Postal code

Phone

Fax

Email

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