

# 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

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Oakha@mazums.ac.ir

**Web page address****Person responsible for scientific inquiries****Contact****Name of organization / entity**

Mazandaran University Of Medical Sciences

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**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*