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 Hirsurism , 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

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**
Double blinded

**Blinding (investigator's opinion)**
Double blinded

**Blinding description**
Placebo

**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
empty
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
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
Oakh@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
Oakh@mazums.ac.ir
Web page address

Person responsible for updating data

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
Oakh@mazums.ac.ir
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