Effects of Letrozole compared with Danazole on patients with confirmed endometriosis: A randomized clinical trial

Protocol summary

Summary
Letrozole is an aromatase inhibitor which can decrease estrogen production in peripheral tissues and endometriosis. Danazole as an androgen inhibits estrogen production in ovaries and recently has been introduced as an aromatase inhibitor. This study was designed to compare the effects of Danazole with Letrozole on endometriosis symptom relief. Materials and methods This was an interventional study. 105 patients with confirmed endometriosis were randomly assigned to one of three groups: Group 1 received Letrozole tablet (2.5mg/day), calcium (1000mg/day) and vitamin D (800 IU/day). Group 2 received Danazole tablet (600mg/day), calcium (1000mg/day) and vitamin D (800 IU/day). Group 3 (placebo group) received 2 calcium tablets/day (each tablet=500mg) and vitamin D (800 IU/day). Pelvic pain, dysmenorrhea and dyspareunia were assessed in participants before study and monthly during the study for six months. Data were analyzed via SPSS version 15 with Friedman and Wilcoxon tests.

General information

Acronym
IRCT registration information
IRCT registration number: IRCT138812043414N1
Registration date: 2010-05-28, 1389/03/07
Registration timing: retrospective

Recruitment status
Recruitment complete

Funding source
Isfahan University of Medical Sciences

Expected recruitment start date
2008-11-21, 1387/09/01

Expected recruitment end date
2009-09-21, 1388/06/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Effects of Letrozole compared with Danazole on patients with confirmed endometriosis: A randomized clinical trial

Public title
Effects of Letrozole compared with Danazole on patients with confirmed endometriosis: A randomized clinical trial

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria were: women in reproductive age with regular menstruation cycles (18 to 45 days), confirmed endometriosis in laparoscopy, chronic pelvic pain and dysmenorrhea for at least 2 weeks in each month during past 3 months. Exclusion criteria were: abnormal vaginal bleeding with unknown cause, ovarian cyst >2cm, hormone therapy during past 3 months, osteopenia, smoking, hypersensitivity to danazole and letrozole, history of convulsion, pulmonary, cardiac, hepatic or renal diseases, cerebrovascular disease and pregnancy

Age
From 18 years old to 44 years old

Gender
Female

Phase
N/A

Groups that have been masked
Secondary outcomes

1
Description
Dysmenorhea
Timepoint
every month
Method of measurement
VAS and pelvic examination

2
Description
Pelvic pain
Timepoint
every month
Method of measurement
VAS and pelvic examination

3
Description
Dysparonia
Timepoint
every month
Method of measurement
VAS and pelvic examination

Intervention groups

1
Description
Letrozole tablet (2.5mg/day), calcium (1000mg/day) and vitamin D (800 IU/day)
Category
Treatment - Drugs

2
Description
Danazole tablet (600mg/day), calcium (1000mg/day) and vitamin D (800 IU/day)
Category
Treatment - Drugs

3
Description
Placebo group received 2 calcium tablets/day (each tablet=500mg) and vitamin D (800 IU/day)
Category
Placebo

Recruitment centers

1
Recruitment center
Alzahra Hospital of Isfahan

Health conditions studied

1
Description of health condition studied
Endometriosis
ICD-10 code
N80
ICD-10 code description
Endometriosis

Primary outcomes

1
Description
Recurrence of endometriosis
Timepoint
Every month
Method of measurement
VAS

Sample size
Target sample size: 105

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
Ethiccommittee of Isfahan Medical University
Street address
Iran.
City
Isfahan
Postal code
816684151

Approval date
2017-11-21, 1396/08/30

Ethics committee reference number
388371

Ethics committees

1
Ethics committee
Name of ethics committee
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Iran.
City
Isfahan
Postal code
816684151

Approval date
2017-11-21, 1396/08/30

Ethics committee reference number
388371
Full name of responsible person
Hatave Ghasemi Tehrany

Street address
Alzahra Hospital

City
Isfahan

Sponsors / Funding sources

1
Sponsor
Name of organization / entity
Medical University of Isfahan
Full name of responsible person
Medical University of Isfahan
Street address
Hezarjerib street.Isfahan
City
Isfahan

Grant name

Grant code / Reference number

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

Title of funding source
Medical University of Isfahan

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
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Full name of responsible person
Dr Hatave Ghasemi Tehrany
Position
Resident of Obstetric and Gynecology

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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
empty