

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

A Randomized controlled clinical trial comparing the effects of aromataseinhibitor(letrozole)and gonadotropin-releasing hormone(triptoreline) on uterine leiomyoma volum

Protocol summary

Summary

Uterine leiomyomas are benign monoclonal tumors arising from the smooth muscle cells of the myometrium. GnRHa are the most common medical therapy for uterine myomas. Since recent discovery in fibroid pathophysiological structure interests in using aromatase inhibitors for treating myomas have been increased. This study was conducted as a randomized clinical trial. Twenty patients with symptomatic uterine myomas randomized into two groups. First group received 25mg letrozol tablet/day 5 days in bleeding phase of menstrual period; the other group received 3.5mg triptorelin intra muscular injection per month. Myomas size was evaluated and documented before and after medical therapy in second, 4th, 6th, and 12th weeks of study. Inclusion criteria were: age between 18 to 50 years old; myoma size ≥ 5 cm with abnormal vaginal bleeding, unexplained infertility, pelvic pain, dysmenorrhea and signs related to mass. Exclusion criteria were: multiple myoma size > 2 cm and hormonal therapy during last month.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201012045307N1**
Registration date: **2011-10-26, 1390/08/04**
Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2011-10-26, 1390/08/04

Registrant information

Name

Mitra Abdoli

Name of organization / entity

Hamedan University of Medical Sciences

Country

Iran (Islamic Republic of)

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+98 81 1827 7012

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Recruitment status

Recruitment complete

Funding source

Hamedan University of Medical Sciences, Shahid Fahmidehe ave.

Expected recruitment start date

2011-01-21, 1389/11/01

Expected recruitment end date

2011-06-20, 1390/03/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A Randomized controlled clinical trial comparing the effects of aromataseinhibitor(letrozole)and gonadotropin-releasing hormone(triptoreline) on uterine leiomyoma volum

Public title

Decapeptid effect in myoma

Purpose

Treatment

Inclusion/Exclusion criteria

Included: Age between 18 to 50 years old; myoma size equal or more than 5 cm with abnormal vaginal bleeding,

unexplained infertility, pelvic pain, dysmenorrhea and signs related to mass. Exclusion criteria: Multiple myoma size more than 2cm and hormonal therapy during last month major disease

Age

From **18 years** old to **50 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **20**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Hamedan University of Medical Sciences

Street address

Hamedan University of Medical Sciences, Shahid Fahmide aven.

City

Hamedan

Postal code

Approval date

2011-01-12, 1389/10/22

Ethics committee reference number

163576/9/35/16/پ

Health conditions studied

1

Description of health condition studied

Myoma

ICD-10 code

M8895/0

ICD-10 code description

Myoma

Primary outcomes

1

Description

Uterus myoma size

Timepoint

Baseline, weeks 2, 4, 6 and 12

Method of measurement

Myoma size with transvaginal sonography(cm)

Secondary outcomes

1

Description

Dysuria

Timepoint

Weeks 2, 4, 6 and 12

Method of measurement

Questionnaire

2

Description

Flushing

Timepoint

Weeks 2, 4, 6 and 12

Method of measurement

Questionnaire

3

Description

Dryness of vagina

Timepoint

Weeks 2, 4, 6 and 12

Method of measurement

Questionnaire

4

Description

Dysparunia

Timepoint

Weeks 2, 4, 6 and 12

Method of measurement

Questionnaire

Intervention groups

1

Description

Tab.Letrozol 2.5 mg at day of mens Amp.Triptorelin3.75 mg evry month(3month)

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Gynecology and Infertility Ward, Fatemie Hospital

Full name of responsible person

Dr. Soghra rabiee

Street address

Fatemie Hospital

City

Hamedan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for Research, Hamedan University of Medical Sciences

Full name of responsible person

Dr. Abas Zamanian

Street address

Hamedan University of Medical Sciences, Shahid Fahmidehe ave.

City

Hamedan

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice Chancellor for Research, Hamedan 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

Hamedan University of Medical Sciences

Full name of responsible person

Dr. Soghra Rabiee

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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