

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Effects of GnRH and Raloxifen on the size of uterine lyomioma

Protocol summary

Summary

Objectives: This study aimed to compare the medical effects of raloxifene and GnRH on uterine lyomioma size. **Design:** 53 women with uterine lyomioma were participated in this study. **Setting and conduct:** This was a randomized controlled trial that it was conducted in Besat hospital in Sanandaj-Iran. Participants were randomly divided into two groups of Raloxifene and GnRH using simple randomization (using computer). 27 patients were allocated in raloxifene group and 26 patients were allocated in GnRH group. **Participants and inclusion and exclusion criteria:** 61 patients were evaluated in the first step. Then 53 patient were entered to the study. Inclusion criteria included not being menopausal, and having lyomiomas with a minimum size of 40 mm and a maximum of 60 mm in one of the diameters of tumor. Exclusion criteria included having metabolic disease, neoplasia disease, infectious diseases, blood disorders, history of venous thrombosis, liver disease, active rheumatoid arthritis, BMI greater than 30 or less than 18 kg/m², hormone therapy in the last 6 months, surgery in the last 6 months, hypoechoic or calcified lyomiomas, endometrial abnormalities in sonography, and lesions of the cervix. **Interventions:** GnRH group received one dose of GnRH per month (3.75mg intramuscular injection) and raloxifene group received a daily dose of raloxifene 60 mg/orally for 3 months. **Main outcome variables:** The size of lyomioma, prior and during the intervention, was determined by a sonographer.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014032816490N2**

Registration date: **2014-04-13, 1393/01/24**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2014-04-13, 1393/01/24

Registrant information

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Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Kurdistan University of Medical Sciences

Expected recruitment start date

2010-11-06, 1389/08/15

Expected recruitment end date

2013-05-05, 1392/02/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effects of GnRH and Raloxifen on the size of uterine lyomioma

Public title

Effects of GnRH and Raloxifen on the size of uterine lyomioma

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: not being menopausal, and having a

history of lyomiomas with a minimum size of 40 mm and a maximum of 60 mm in one of the diameters of tumor. Exclusion criteria: having metabolic disease, neoplasia disease, infectious diseases, blood disorders; history of venous thrombosis, liver disease, active rheumatoid arthritis; BMI greater than 30 or less than 18 kg/m2; hormone therapy in the last 6 months; surgery in the last 6 months; hypoechoic or calcified lyomiomas; endometrial abnormalities in sonography, and lesions of the cervix.

Age

No age limit

Gender

Female

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: 53

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Single blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Kurdistan University of Medical Sciences

Street address

Vice chancellor for research, Medicine School, Pasdaran Ave

City

Sanandaj

Postal code

6617713446

Approval date

2010-10-24, 1389/08/02

Ethics committee reference number

89/43/پ

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

Uterine lyomioma

ICD-10 code

N85.9

ICD-10 code description

Noninflammatory disorder of uterus, unspecified

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

Uterine leiomyomas size

Timepoint

Before and 90 days after treatment

Method of measurement

Sonography

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

Endometrial thickness

Timepoint

Before and 90 days after treatment

Method of measurement

Sonography

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

The intervention group 2 was consisted of 26 patients; they were treated using GnRH one dose per month (3.75mg intramuscular injection).

Category

Treatment - Drugs

2**Description**

Intervention group 1 was consisted of 27 patients who were received a daily dose of raloxifene 60 mg/orally for 3 months.

Category

Treatment - Drugs

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

Besat Hospital, Kurdistan University of Medical Sciences

Full name of responsible person

Farnaz Zandvakili

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x

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Vice chancellor for research, Kurdistan University of Medical Sciences

Full name of responsible person
Dr Ataollah Heidari

Street address
Vice chancellor for research, Medicine School, Pasdaran Ave

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Sanandaj

Grant name

طرح غیر HSR

Grant code / Reference number
1389/43

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

Title of funding source
Vice chancellor for research, Kurdistan 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
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Full name of responsible person
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Position
Associated Professor

Other areas of specialty/work

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x

Person responsible for updating data

Contact

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x

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