

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 May 2026

Study of requirement to myomectomy in women`s with symptomatic myoma (fibroid) after the injection of Triptorelin acetate (decapeptyl)

Protocol summary

Summary

The aim of this study is the evaluation of requirement to myomectomy in women with symptomatic (too bleeding) myoma (fibroids) after the injection of Triptorelin acetate (Decapeptyl). Interventional study with Parallel pattern designed and sampling is randomly for case and control groups. The total sample size was 48. 24 patients in control group and 24 in experimental group. Inclusion criteria: women with myoma are not menopausal and do not use other medicines to improve myoma. Exclusion criteria: patient disagreement to participate in the study. Women with myoma were randomly divided into control and test groups. In the experimental group, after routine examination, Decapeptyl 3/75 mg injected intramuscularly in the gluteal region and dorsogluteal deeply once every 28 days for 6 months (Intervention on days 28, 56, 84, 112, 140 and 168 of the cycle). The control group will using Dydrogesterone 20mg to reduce the symptoms of myoma from the 5th day of menstrual cycle for 20 days. About the ability of decapeptyl to improve myoma and decrease surgeries there is different responses in different places. This study is triple blinde and Blinding is done for patients in the study, participants were evaluated to measure the outcome and the committee.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015041421653N1**
Registration date: **2015-06-15, 1394/03/25**
Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2015-06-15, 1394/03/25

Registrant information

Name

Athar Rasekh Jahromi

Name of organization / entity

Jahrom University of Medical Sciences

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Iran (Islamic Republic of)

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+98 71 5432 6602

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Recruitment status

Recruitment complete

Funding source

Jahram University of Medical Sciences

Expected recruitment start date

2015-07-23, 1394/05/01

Expected recruitment end date

2016-01-21, 1394/11/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Study of requirement to myomectomy in women`s with symptomatic myoma (fibroid) after the injection of Triptorelin acetate (decapeptyl)

Public title

Requirement to myomectomy in women with myoma(fibroid) after treatment

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: non menopausal wemon with myoma; not using another drugs; myoma has symptoms like pain and bleeding even with small size but large number.

Exclusion criteria:menopausal women; using another drugs except decapeptyl for treatment; notsymptomatic myoma; allergic or intestinal reactions after getting drug.

Age

No age limit

Gender

Female

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: 48

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Triple blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Jahrom University of Medical Sciences

Street address

Motahari Street, Jahrom, Fars

City

Jjahrom

Postal code

Approval date

2015-03-21, 1394/01/01

Ethics committee reference number

Jums.REC.1393.100

Health conditions studied

1

Description of health condition studied

leiomyoma

ICD-10 code

D25

ICD-10 code description

benign neoplasms of uterus with morphology code M889 and behaviour code /0

Primary outcomes

1

Description

Lleiomyoma Size

Timepoint

Intervention on days 28, 56, 84, 112, 140 and 168 of the cycle

Method of measurement

mm. sonography

Secondary outcomes

1

Description

Frequency of myomectomy

Timepoint

End of study

Method of measurement

Enumeration

Intervention groups

1

Description

Intervention group: Dcapeptyl 3/75 mg dose will injected intramuscularly in the gluteal region and by dorsogluteal pattern and deeply once every 28 days for 6 months (intervention on days 28, 56, 84, 112, 140 and 168 cycles menstruation).

Category

Treatment - Drugs

2

Description

control group: control group will using Dydrogesterone 20mg from the 5th day of menstrual cycle for 20 days.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Doctor Athar Rasekh Jahromi Clinic

Full name of responsible person

Athar Rasekh Jahromi

Street address

Farmandari Street, Jahrom, Fars

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Jahrom

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Jahram University of Medical Sciences
Full name of responsible person
Abas Rahmnia
Street address
Motahari Street, Jahrom, Fars
City
Jahrom
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Jahram 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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Person responsible for updating data

Contact

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