Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Effect off Microrelin (GnRH agonist) on uterine fibroma

Protocol summary

Summary

GnRH agonist are available as base, acetate, diacetate or ambonate. According to existing limitations in medical market in Iran it is supposed to focus on domestic production. No other study is done on the effect of this group of drugs on myoma size in Iran. This is a randomized clinical trial. In the age range of 18 to 50 years (all pre menopausal) patients candidate for hysteroscopic myoma resection are randomly divided into two groups of treatment and control (n= 30 for each group). Intervention is using microrelin in treatment group. Treatment is started in first 5 days of menstrual cycle by 3.7 mg depot ampule and is repeated for three consecutive cycles. Randomization in done by a nurse in clinic using random blocks. Serum levels of FSH, LH and estradiol are measured in weeks 0, 2 and 12 after beginning of the study. The size of myoma are measured using sonography before microrelin administration and before surgery. Feasibility of myoma resection, operation time recorded by the surgeon and the volume of fluid absorption during the operation are compared in two groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201408133950N3**
Registration date: **2014-11-22, 1393/09/01**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2014-11-22, 1393/09/01

Registrant information

Name

Mina Jafarabadei

Name of organization / entity

Tehran University of Medical Sciences

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Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for research of Tehran University of Medical Sciences

Expected recruitment start date

2014-04-04, 1393/01/15

Expected recruitment end date

2014-08-31, 1393/06/09

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect off Microrelin (GnRH agonist) on uterine fibroma

Public title

Effect of Microrelin on the size of uterus fibroma in patients undergoing hysteroscopic myoma resection

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion Criteria: Be a pre-menopausal woman between 18 and 50 years, have indication of surgical myomectomy due to any complain, Less than 2 myomas with the diameter of 2- 4 Cm which are totally intracavitary or have a myometrial expansion less than 50%, If of childbearing potential the subject must be practicing a non-hormonal method of contraception, BMI ≥ 18 and ≤ 40. Exclusion Criteria: Indication of emergent surgery, history of or current uterine cervical, ovarian or

breast cancer, current endometrium atypical hyperplasia or adenocarcinoma, a known severe coagulation disorder, has a history of or current treatment for myoma with a Selective Progesterone Receptor Modulator (SPRM) or a GnRH-agonist, Has a history of or known current osteoporosis, abnormal hepatic function at study entry, a positive pregnancy test at baseline or is nursing or planning a pregnancy during the course of the study, a current (within twelve months) problem with alcohol or drug abuse, is currently enrolled in an investigational drug or device study or has participated in such a study within the last 30 days.

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

Gender
Female

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **60**

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
Ethics committee of research deputy, Tehran University of Medical Sciences

Street address
Tehran University of Medical Sciences, Ghods building, Keshavarz blvd., Tehran.

City
Tehran

Postal code

Approval date
2014-07-20, 1393/04/29

Ethics committee reference number
92-03-39-23336

Health conditions studied

1

Description of health condition studied
Leiomyoma of uterus

ICD-10 code
D25

ICD-10 code description
Leiomyoma of uterus

Primary outcomes

1

Description
size of myoma

Timepoint
12 weeks after microrelin subscription

Method of measurement
sonography

Secondary outcomes

1

Description
level of gonadotrophins and estrogen in serum

Timepoint
two and 12 weeks after microrelin subscription

Method of measurement
ELISA

2

Description
Surgeon's satisfaction

Timepoint
end of operation

Method of measurement
Visual Assessment Score

3

Description
Operation time

Timepoint
end of operation

Method of measurement
surjeon's announcement

4

Description
Absorbed fluide volume

Timepoint
end of operation

Method of measurement
fluide gathered in suction subtracted from used fluide

Intervention groups

1

Description
intervention is using microrelin in treatment group. Treatment is started in first 5 days of menstrual cycle by 3.7 mg depot ampule and is repeated for three consecutive cycles.
Category
Treatment - Drugs

2

Description
Control Group: no treatment
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Reproductive Health Research Center, Tehran University of medical Sciences
Full name of responsible person
Mina Jafarabadi
Street address
Reproductive Health Research Center, Emam Hospital Complex, Keshavarz Blvd.,
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice Chancellor for Research of Tehran University of Medical sciences
Full name of responsible person
Mrs Mostufi
Street address
Qods building, Keshavarz Blvd.,
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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 of Tehran 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

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reseach expert

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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