# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

04 Jun 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

**Country**

Iran (Islamic Republic of)

**Phone**

+98 21 6658 1616

**Email address**

jafarabadi@tums.ac.ir

**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.,
**City**
Tehran

## 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.,
**City**
Tehran
**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**
Reproductive Health research center
**Full name of responsible person**
Mina Jafarabadi
**Position**
M.D.
**Other areas of specialty/work**
**Street address**
Emam Hospital, Keshavarz Blvd., Tehran, Iran
**City**
Tehran
**Postal code**
**Phone**
+98 21 6658 1616
**Fax**
+98 21 6658 1658
**Email**
jafarabadi@tums.ac.ir
**Web page address**

## Person responsible for scientific inquiries

**Contact**
**Name of organization / entity**
Reproductive Health Research Center
**Full name of responsible person**
Mina Jafarabadi
**Position**
M.D.
**Other areas of specialty/work**
**Street address**
Emam Hospital, Keshavarz Blvd.,
**City**
Tehran
**Postal code**
14194
**Phone**
+98 21 6658 1616
**Fax**
+98 21 6658 1658
**Email**
jafarabadi@tums.ac.ir
**Web page address**

## Person responsible for updating data

**Contact**
**Name of organization / entity**
Reproductive Health Research Center
**Full name of responsible person**
Fedyeh Haghollahi
**Position**
reseach expert

**Other areas of specialty/work**

**Street address**

Reproductive Health Research Center, Imam Hospital, Keshavarz BlVd.,

**City**

Tehran

**Postal code**

14194

**Phone**

+98 21 6658 1616

**Fax**

+98 21 6658 1658

**Email**

fedyeh_hagh@yahoo.com

**Web page address**

## 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*