# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

06 Jul 2026

## Comparison of the Effectiveness of Simvastatin on Uterine Leiomyoma Development in Infertile Women

### Protocol summary

**Study aim**
Comparison of the Effectiveness of Simvastatin on Uterine Leiomyoma Development in Infertile Women

**Design**
A randomized, double-blind controlled clinical trial with parallel groups design of 60 patients

**Settings and conduct**
60 eligible infertile patients with uterine fibroid who will refer to infertility clinic of Royan Institue for infertility treatment and are underwent ART will be entered the study with ethic consideration.

**Participants/Inclusion and exclusion criteria**
• Women with age between 20-40 years, intramural fibroids confirmed by ultrasound, presence of at least one fibroid with size >4 cm or two fibroids with size >3 cm detected by pelvic ultrasound, presence of at least 3 fibroids with size <3 cm and a history of 2 IVF failures, number of fibroids ≤ 5, Body Mass Index >25 Kg/m2 include the study. The women with severe male factor infertility, severe endometriosis, diminished ovarian reserve, breastfeeding, Pregnancy, Hb ≤ 7, alcohol consumption, allergic to simvastatin, signs or symptoms of muscle aches, muscle weakness, myopathic syndrome, mental illness, hepatic dysfunctions, renal disease, cardiovascular disease, hypotension ,diabetes mellitus, hypothyroidism, neuropathy, lupus, cataract and cancer, transaminase abnormalities and taking antifungal medications, lipid-lowering medications (gemfibrozil, clofibrate and...), warfarin, danazol and erythromycin in the last one month don't include the study.

**Intervention groups**
Patients will be randomly divided into three groups and will be randomized to receive simvastatin 40 mg orally + vaginal placebo; simvastatin 40 mg vaginally + oral placebo and vaginal placebo + oral placebo for 3 months.

**Main outcome variables**
Uterine fibroid size, Uterine size, uterine bleeding

### General information

**Reason for update**

**Acronym**

**IRCT registration information**
IRCT registration number: **IRCT20080831001141N34**
Registration date: **2021-01-01, 1399/10/12**
Registration timing: **registered_while_recruiting**

Last update: **2021-01-01, 1399/10/12**
Update count: **0**

**Registration date**
2021-01-01, 1399/10/12

**Registrant information**

**Name**
Kiandokht Kiani

**Name of organization / entity**
Royan Institute

**Country**
Iran (Islamic Republic of)

**Phone**
+98 21 2230 7960

**Email address**
kiandokht.kiani@royaninstitute.org

**Recruitment status**
**Recruitment complete**

**Funding source**

**Expected recruitment start date**
2016-08-01, 1395/05/11

**Expected recruitment end date**
2021-09-14, 1400/06/23

**Actual recruitment start date**
empty

**Actual recruitment end date**
empty

**Trial completion date**
empty

**Scientific title**
Comparison of the Effectiveness of Simvastatin on Uterine Leiomyoma Development in Infertile Women

**Public title**
Effect of Simvastatin in Treatment of Uterine Leiomyoma

**Purpose**
Treatment

**Inclusion/Exclusion criteria**

**Inclusion criteria:**
Age between 20-39 years Intramural Fibroids confirmed by ultrasound Presence of at least one fibroid with size >4 cm or two fibroids with size >3 cm detected by pelvic ultrasound. Presence of at least 3 fibroids with size <3 cm and a history of 2 IVF failures. Number of fibroids ≤ 5 Body Mass Index >25 Kg/m2

**Exclusion criteria:**
Severe male factor Severe endometriosis Diminished ovarian reserve Breastfeeding Pregnancy Alcohol consumption Allergic to simvastatin Signs or symptoms of Muscle aches, muscle weakness, myopathic syndrome, mental illness, hepatic dysfunctions, renal disease, Cardiovascular disease, hypotension ,diabetes mellitus, hypothyroidism, neuropathy, lupus, cataract and cancer Transaminase abnormalities Hb ≤ 7 Taking antifungal medications, Lipid-Lowering medications (gemfibrozil, clofibrate and...), warfarin, danazol and erythromycin in the last one month

**Age**
From **20 years** old to **39 years** old

**Gender**
Female

**Phase**
N/A

**Groups that have been masked**

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

**Sample size**
Target sample size: **60**

**Randomization (investigator's opinion)**
Randomized

**Randomization description**
A randomization list was provided by statistic using randomization website (block randomization with block size of 6) and allocation was performed by a third party not directly connected with the trial.

**Blinding (investigator's opinion)**
Double blinded

**Blinding description**
As soon as the patient is entered into the study, the treatment code is determined from the randomly generated sequence and a unique identification code is assigned to the patient. Random codes are stored in the main project management unit of the study and are inqueried through the clinical caregiver and the relevant intervention will be applied to the new patient. For this purpose, after determining the patient eligibility, the clinical caregiver, inquiries from the project management unit and announces the patient information and receives the patient's assigned identification and treatment code. Therefore, the clinical caregiver will not be aware of the allocative treatment until the patient is admitted. The drug Medicine packages are given to the clinical caregiver by the code they are registered with. All placebo tablets are provided by Hakim Pharmaceutical Company (Tehran, Iran), approved by the Iranian Food and Drug Administration. The appearance of placebo tablets is in color, shape and size quite similar to simvastatin tablets, which cannot be detected by patients, clinical care giver and researcher.

**Placebo**
Used

**Assignment**
Parallel

**Other design features**
CBC, Lipid profile, kidney & Liver function tests, FBS & hormonal evaluation will be performed before and after the treatment. Ultrasound examination will be performed before and after the treatment for determining of the number, size, and site of the myoma and also size of the uterus. Pictorial Blood Loss Assessment Chart (PBLAC) and Visual Analogue Scale (VAS) will be filled before and after the treatment.

## Secondary Ids

### 1

**Registry name**
**Secondary trial Id**
**Registration date**
2017-04-28, 1396/02/08

## Ethics committees

### 1

**Ethics committee**

**Name of ethics committee**
Ethics committee of Royan Institute

**Street address**
Number 12, East Hafez Avenue, Bani Hashem Street, Resalat Highway, Tehran, Iran

**City**
Tehran

**Province**
Tehran

**Postal code**
1665659911

**Approval date**
2015-12-08, 1394/09/17

**Ethics committee reference number**
IR.ACECR.ROYAN.REC.1394.51

## Health conditions studied

### 1

**Description of health condition studied**

Uterine Fibroid

**ICD-10 code**

D25

**ICD-10 code description**

Leiomyoma of uterus

## Primary outcomes

### 1

**Description**

Uterine fibroid size

**Timepoint**

Before and 3 months after starting the treatment

**Method of measurement**

Evaluation the size of uterine fibroid with ultrasound

## Secondary outcomes

### 1

**Description**

Uterine size

**Timepoint**

Before and 3 months after starting the treatment

**Method of measurement**

Evaluation the uterine size with ultrasound

### 2

**Description**

Menstrual bleeding

**Timepoint**

Before and 3 months after starting the treatment

**Method of measurement**

Validated pictorial blood loss assessment chart

### 3

**Description**

Dysmenorrhea

**Timepoint**

Before and 3 months after starting the treatment

**Method of measurement**

Visual analog scale

## Intervention groups

### 1

**Description**

Intervention group1: The patients with uterine fibroid will receive simvastatin 40mg orally+ vaginal placebo every day for 3 months.

**Category**

Treatment - Drugs

### 2

**Description**

Intervention group 2: The patients with uterine fibroid will receive simvastatin 40mg vaginally + oral placebo every day for 3 months.

**Category**

Treatment - Drugs

### 3

**Description**

Control group: The patients with uterine fibroid will receive Vaginal placebo+ oral placebo every day for 3 months.

**Category**

Placebo

## Recruitment centers

### 1

**Recruitment center**

**Name of recruitment center**

Infertility Center of Royan Institute

**Full name of responsible person**

Abdolhossein Shahverdi

**Street address**

Number 12, East Hafez Avenue, Bani Hashem Street, Resalat Highway, Tehran, Iran

**City**

Tehran

**Province**

Tehran

**Postal code**

1665659911

**Phone**

+98 21 2356 2211

**Email**

Shahverdi@royaninstitute.org

## Sponsors / Funding sources

### 1

**Sponsor**

**Name of organization / entity**

Royan Institute

**Full name of responsible person**

Abdolhossein Shahverdi

**Street address**

Number 12, East Hafez Avenue, Bani Hashem Street, Resalat Highway, Tehran, Iran

**City**

Tehran

**Province**

Tehran

**Postal code**

1665659911

**Phone**

+98 21 2356 2211

**Email**

Shahverdi@royaninstitute.org

**Grant name**

**Grant code / Reference number**

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

Yes

**Title of funding source**
Royan Institute

**Proportion provided by this source**
100

**Public or private sector**
Public

**Domestic or foreign origin**
Domestic

**Category of foreign source of funding**
*empty*

**Country of origin**

**Type of organization providing the funding**
Other

## Person responsible for general inquiries

**Contact**

**Name of organization / entity**
Royan Institute

**Full name of responsible person**
Mahnaz Ashrafi

**Position**
Professor

**Latest degree**
Specialist

**Other areas of specialty/work**
Gynecology and Obstetrics

**Street address**
Number 12, East Hafez Avenue, Bani Hashem Street, Resalat Highway, Tehran, Iran

**City**
Tehran

**Province**
Tehran

**Postal code**
1665659911

**Phone**
+98 21 2356 2645

**Email**
ashrafim@royaninstitute.org

## Person responsible for scientific inquiries

**Contact**

**Name of organization / entity**
Royan Institute

**Full name of responsible person**
Mahnaz Ashrafi

**Position**
Professor

**Latest degree**
Specialist

**Other areas of specialty/work**
Gynecology and Obstetrics

**Street address**
Number 12, East Hafez Avenue, Bani Hashem Street, Resalat Highway

**City**
Tehran

**Province**
Tehran

**Postal code**
1665659911

**Phone**
+98 21 2356 2645

**Email**
ashrafim@royaninstitute.org

## Person responsible for updating data

**Contact**

**Name of organization / entity**
Royan Institute

**Full name of responsible person**
Nadia Jahangiri

**Position**
Researcher

**Latest degree**
Master

**Other areas of specialty/work**
Midwifery

**Street address**
Number 12, East Hafez Avenue, Bani Hashem Street, Resalat Highway

**City**
Tehran

**Province**
Tehran

**Postal code**
1665659911

**Phone**
+98 21 2356 2645

**Email**
jahangiri_n@yahoo.com

## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**
Undecided - It is not yet known if there will be a plan to make this available

**Study Protocol**
Undecided - It is not yet known if there will be a plan to make this available

**Statistical Analysis Plan**
Not applicable

**Informed Consent Form**
Undecided - It is not yet known if there will be a plan to make this available

**Clinical Study Report**
Undecided - It is not yet known if there will be a plan to make this available

**Analytic Code**
Undecided - It is not yet known if there will be a plan to make this available

**Data Dictionary**
Not applicable