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

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Email

Shahverdi@royaninstitute.org

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Royan Institute

Full name of responsible person

Abdolhossein Shahverdi

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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
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

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Person responsible for scientific inquiries

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Other areas of specialty/work
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Person responsible for updating data

Contact

Name of organization / entity
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Full name of responsible person
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Position
Researcher

Latest degree
Master

Other areas of specialty/work
Midwifery

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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