

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Investigating the protective effect of simvastatin on inflammatory factors in infertile women who are candidates for In vitro fertilization (IVF)

#### Protocol summary

##### Study aim

Evaluation of the effect of simvastatin on inflammatory factors of infertile women

##### Design

A double-blind randomized clinical trial with parallel groups, phase 2/3 on 84 patients. Sealedenvelope.com will be used for randomization.

##### Settings and conduct

The study will be conducted at Shahid Akbarabadi Hospital, Tehran, Iran. Eligible women with unexplained infertility with are included in the study in two groups of 42 individuals. The serum level of inflammatory factors will be measured before and after the study, and the results of their artificial insemination treatment will be evaluated until clinical pregnancy is determined. In this study, patients, health care providers and outcome assessors will be blinded.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: infertile women of unknown cause aged 20-40 years and serum level of tumor necrosis factor-alpha (TNF $\alpha$ ) higher than 5 pg/ml. Exclusion criteria: history of any liver, kidney, metabolic, and muscle disorders, history of taking drugs related to cardiovascular, nervous, and metabolic systems.

##### Intervention groups

Simvastatin receiving group, placebo receiving group

##### Main outcome variables

Serum levels of tumor necrosis factor-alpha (TNF $\alpha$ ) and interleukin 1, clinical pregnancy, number and percentage of adverse events

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20200421047152N3**

Registration date: **2023-08-21, 1402/05/30**

Registration timing: **prospective**

Last update: **2023-08-21, 1402/05/30**

Update count: **0**

##### Registration date

2023-08-21, 1402/05/30

##### Registrant information

###### Name

Arash Mohazzab

###### Name of organization / entity

Avicenna Research Institute

###### Country

Iran (Islamic Republic of)

###### Phone

+98 21 2351 9630

###### Email address

amohazzab@yahoo.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2023-09-06, 1402/06/15

##### Expected recruitment end date

2024-04-18, 1403/01/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Investigating the protective effect of simvastatin on inflammatory factors in infertile women who are candidates for In vitro fertilization (IVF)

##### Public title

Protective effect of simvastatin on inflammatory factor

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

**Inclusion criteria:**

Women between 20-40 years old with unexplained infertility Serum Tumor Necrosis Factor (TNF $\alpha$ ) > 5 pg/ml

**Exclusion criteria:**

History of liver, kidney and muscular diseases History of metabolic diseases such as diabetes or thyroid dysfunction History of organic or function genital disorder History of medication with neurological , cardiovascular and metabolic drugs

**Age**

From **20 years** old to **40 years** old

**Gender**

Female

**Phase**

2-3

**Groups that have been masked**

- Participant
- Care provider
- Investigator
- Outcome assessor

**Sample size**

Target sample size: **84**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Block randomization will be done with a block size of 6. Sealedenvelode.com software will be used to generate a random sequence. For concealment, the generated sequence will be provided to a third party independent of the study team and will be revealed individually to the allocating person using A and B codes.

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

This study will use a placebo similar in shape and color to simvastatin for blinding. An independent pharmaceutical company manufactures this placebo. Patients are generally aware of the existence of the placebo group in the study, but they are unaware of the group in which they are personally placed. Pills will be given to the care provider and then to the patients in identical packages with A and B coding.

**Placebo**

Used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

IUMS Biomedical Research Ethics Committee

**Street address**

Next to Milad Tower ,Hemat Highway

**City**

Tehran

**Province**

Tehran

**Postal code**

1134845764

**Approval date**

2021-06-07, 1400/03/17

**Ethics committee reference number**

IR.IUMS.FMD.REC.1400.155

**Health conditions studied****1****Description of health condition studied**

Unexplained female infertility

**ICD-10 code**

N97.8

**ICD-10 code description**

Female infertility of other origin

**Primary outcomes****1****Description**

Serum level of Tumor Necrosis Factor (TNF $\alpha$ )

**Timepoint**

Screening, End of intervention (day 45)

**Method of measurement**

Elisa technique

**Secondary outcomes****1****Description**

Interleukin 1 serum level

**Timepoint**

Screening, End of intervention (day 45)

**Method of measurement**

Elisa technique

**2****Description**

Human chorionic gonadotropin Beta ( $\beta$ hCG)

**Timepoint**

Two weeks after embryo transfer

**Method of measurement**

Elisa technique

**3****Description**

C reactive protein serum level

**Timepoint**

Screening, End of intervention (day 45)

**Method of measurement**

Immunoturbidimetry

#### 4

**Description**

Clinical Pregnancy

**Timepoint**

5 weeks after embryo transfer

**Method of measurement**

Detection of fetal heart rate (FHR) in trans-vaginal ultrasound

#### 5

**Description**

Adverse Events

**Timepoint**

During the study period from randomization to the end of the first month after embryo transfer

**Method of measurement**

Interview and physical examination

### Intervention groups

#### 1

**Description**

Intervention group: Patients of this group will receive simvastatin 20 mg daily orally for 45 days before the start of the ovarian stimulation cycle. After the end of the intervention, ovarian stimulation will be done using a gonadotropin-releasing hormone (GnRH) antagonist treatment regimen. Then, after the ovarian puncture, they will undergo in vitro fertilization (IVF) and embryo transfer.

**Category**

Treatment - Drugs

#### 2

**Description**

Control group: Patients in this group will receive a placebo, which is identical with simvastatin tablets in form, orally for 45 days before the start of the ovarian stimulation cycle. After the end of this period, ovarian stimulation will be done through a gonadotropin-releasing hormone (GnRH) antagonist treatment regimen. and then after ovarian puncture, they will be subjected to vitro fertilization (IVF) and embryo transfer.

**Category**

Placebo

### Recruitment centers

#### 1

**Recruitment center****Name of recruitment center**

Akbar Abadi Hospital

**Full name of responsible person**

Mojgan Javedani

**Street address**

Bagh-ferdous station, Molavi street

**City**

Tehran

**Province**

Tehran

**Postal code**

1168743514

**Phone**

+98 21 5560 6034

**Email**

javedani46@yahoo.com

### Sponsors / Funding sources

#### 1

**Sponsor****Name of organization / entity**

Iran University of Medical Sciences

**Full name of responsible person**

Reza Falak

**Street address**

Next to Milad Tower, Hemat Highway

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**Postal code**

۱۴۴۹۶۱۴۵۳۵

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+98 21 86701

**Email**

falak.r@iums.ac.ir

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Iran University of Medical Sciences

**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**

Academic

### Person responsible for general inquiries

**Contact****Name of organization / entity**

Iran University of Medical Sciences

**Full name of responsible person**

Azra Motaghinejad

**Position**

Gyn Resident

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Gynecology and Obstetrics

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**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Iran University of Medical Sciences

**Full name of responsible person**

Mojgan Javedani

**Position**

Associate Professor

**Latest degree**

Subspecialist

**Other areas of specialty/work**

Gynecology and Obstetrics

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**Person responsible for updating data****Contact****Name of organization / entity**

Iran University of Medical Sciences

**Full name of responsible person**

Arash Mohazzab

**Position**

Research Staff

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Epidemiology

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**Email**

amohazzab@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**

No - There is not a plan to make this available

**Informed Consent Form**

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

**Clinical Study Report**

No - There is not a plan to make this available

**Analytic Code**

No - There is not a plan to make this available

**Data Dictionary**

No - There is not a plan to make this available