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 (TNFα) 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 (TNFα) 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
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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 (TNFα) > 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 (TNFα)

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
Humanuman chorionic gonadotropin Beta (βhCG)

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
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person
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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
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 updating data

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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
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