Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

A clinical trial of the effect of salpingectomy on ovarian reserve in women undergoing hysterectomy.

Protocol summary

Study aim

Objective: The aim of this study is to determine the effect of salpingectomy on ovarian reserve in women who are candidates for hysterectomy.

Design

Study design: Randomized double-blind clinical trial. Patients will be randomly assigned in two groups, using a random number sequence, generated with a computer software, according to a randomized block design. The randomization list will be created by the clinical trial's epidemiologist, who keeps the codes until the completion of the study.

Settings and conduct

Among patinets referred to Shabihkhani Clinic affiliated to Kashan University of Medical Sciences, 86 patients will be selected according to inclusion and exclusion criteria. Participants, investigators or the assessors of the outcomes are unaware of the study groups.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Premenopausal women aged 30 to 50 years who are undergoing hysterectomy referred to shabihkhani clinic. No menopause symptoms. FSH<10 IU. Exclusion criteria: A history of pelvic surgery, existence of ovarian mass in sonography before the surgery, smoking, OCP consumption at least for 6 months.

Intervention groups

Intervention group: The patients undergo hysterectomy and salpangectomy. Control group: The patients undergo only hysterectomy.

Main outcome variables

Primary outcome: Serum anti-mullerian hormone levels. Secondary outcome: FSH serum levels.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170513033941N46**
Registration date: **2019-01-22, 1397/11/02**
Registration timing: **retrospective**

Last update: **2019-01-22, 1397/11/02**
Update count: **0**

Registration date

2019-01-22, 1397/11/02

Registrant information

Name

Mohammadreza Sharif

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 5546 3378

Email address

ostadmohammadi-vr@kaums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2016-12-09, 1395/09/19

Expected recruitment end date

2017-06-21, 1396/03/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A clinical trial of the effect of salpingectomy on ovarian reserve in women undergoing hysterectomy.

Public title

Effect of salpingectomy in women undergoing

hysterectomy.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Premenopausal women aged 30 to 50 years who are undergo hysterectomy referred to shabihkhani clinic. No menopause symptoms FSH<10 IU.

Exclusion criteria:

A history of pelvic surgery Existence of ovarian mass in sonography before the surgery smoking OCP consumption at least for 6 months.

Age

From **30 years** old to **50 years** old

Gender

Female

Phase

3

Groups that have been masked

- Participant
- Investigator
- Outcome assessor

Sample size

Target sample size: **86**

Randomization (investigator's opinion)

Randomized

Randomization description

After obtaining informed consent, patients will be randomly assigned in two groups, using a random number sequence, generated with a computer software, according to a randomized block design. The randomization list will be created by the clinical trial's epidemiologist, who keeps the codes until the completion of the study.

Blinding (investigator's opinion)

Double blinded

Blinding description

Allocation concealment will be done by having procedure indicator cards inside a set of numbered opaque sealed envelopes. Patients will be allocated to treatment groups by the author opening the next numbered envelope, after screening, in the presence of the patient. None of the staff or patients will have access to the randomization codes during the study. A patient's treatment assignment will only be unblended when knowledge of the treatment was essential for the further management of the patient. The surgeon performing the procedures will be blinded to the treatment allocation until the time of surgery.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Kashan University of Medical Sciences

Street address

Ghotbe Ravandi Boulevard, Kashan

City

Kashan

Province

Isfehan

Postal code

8115187159

Approval date

2016-12-07, 1395/09/17

Ethics committee reference number

IR.KAUMS.REC.1395.93

Health conditions studied

1

Description of health condition studied

Uterine bleeding

ICD-10 code

N92.6

ICD-10 code description

Irregular menstruation, unspecified

Primary outcomes

1

Description

Serum anti-mullerian hormone levels

Timepoint

Before surgery and 3 months after intervention

Method of measurement

Elisa kit

Secondary outcomes

1

Description

FSH serum level

Timepoint

Before surgery and 3 months after intervention

Method of measurement

Elisa kit

Intervention groups

1

Description

Intervention group: The patients undergo hysterectomy and salpangectomy.

Category
Treatment - Surgery

2

Description
Control group: The patients undergo only hysterectomy.
Category
Treatment - Surgery

Recruitment centers

1

Recruitment center
Name of recruitment center
Shabihkhani Clinic
Full name of responsible person
Dr. Saba Allamezade Davani
Street address
Shahid Beheshti Avenue, Kashan
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Kashan University of Medical Sciences
Full name of responsible person
Dr. Hamidreza Banafshe
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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
Kashan 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
Kashan University of Medical Sciences
Full name of responsible person
Dr. Saba Allamezade Davani
Position
Gynecologist
Latest degree
Specialist
Other areas of specialty/work
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Person responsible for updating data

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