Clinical Trial Protocol
Iranian Registry of Clinical Trials

29 May 2026

Comparison of ovarian reserve after abdominal hysterectomy with& without bilateral salpingectomy in women in reproductive age.

Protocol summary

Study aim
Comparison of ovarian reserve after abdominal hysterectomy with& without bilateral salpingectomy in women in reproductive age

Design
Randomized clinical trial with a control group,parallel groups, no blinding,with 60 patients in two groups of 30 and computer-designed randomization method was used for randomization.

Settings and conduct
In this clinical trial study, all eligible patients of childbearing age will enter the study at the Rouhani Hospital in Babol during the year2021. This surgery is performed by an experienced surgical team of obstetricians and gynecologists of Babol University of Medical Sciences. In patients, ultrasound and tests will be repeated 3 months later

Participants/Inclusion and exclusion criteria
Patients of reproductive age; No history of oligo menorrhagia; Candidate for abdominal hysterectomy with ovarian preservation; No menopausal symptoms and FSH less than 10 units / liter Patients with premenopause or a family history of genital or breast cancers; Reported ovarian cyst; History of taking hormonal drugs during the two months before surgery

Intervention groups
Intervention: Patients in this group underwent abdominal hysterectomy. After round ligament amputation,the eutrophic ligament is isolated instead of infendibloplovik and the ovary (one or both ovaries) is preserved and then, according to the routine protocol of arterial and uterine vein surgery, ligament The cardinal and vaginal cuffs are separated and the uterus and fallopian tubes are removed Control group: Patients in this group during abdominal hysterectomy at the junction of the tubes to the uterus as well as the ectopic ligament are separated and the tubes and ovaries (one or both ovaries and tubes) are preserved. The vagina is removed and the uterus is removed.

Main outcome variables
Comparison of changes in serum levels of antimullerian hormone in the three months after surgery in the two groups

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20210911052439N1**
Registration date: **2021-10-03, 1400/07/11**
Registration timing: **registered_while_recruiting**

Last update: **2021-10-03, 1400/07/11**
Update count: **0**

Registration date
2021-10-03, 1400/07/11

Registrant information
Name
mahboobeh mohammadpour
Name of organization / entity
Country
Iran (Islamic Republic of)
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+98 11 3220 8726
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mahboobehmohammadpour@gmail.com

Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2021-09-23, 1400/07/01
Expected recruitment end date
2022-03-20, 1400/12/29
Actual recruitment start date
empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison of ovarian reserve after abdominal hysterectomy with& without bilateral salpingectomy in women in reproductive age.

Public title
Ovarian reserve after abdominal hysterectomy.
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
All patients in reproductive age without a history of oligomenorrhea who candidates for hysterectomy. Patients with no menopausal symptoms and FSH levels less than 10 units / liter. Patients who are candidates for abdominal hysterectomy without oophorectomy because of benign reasons.
Exclusion criteria:
Patients in premenopausal age. Patients with a family history of genital or breast cancers. Patients whose ovarian cysts have been reported in previous ultrasound examinations. Patients who have a history of taking hormonal or ocp medications within two months before surgery.
Age
To **45 years** old
Gender
Female

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
Patients will be randomly assigned to two groups of 30 using 6 blocks and a ratio of 1: 1. The free website www.randomization.com will be used for the allocation sequence. The obtained sequence will be written in separate sheets and will be placed in sealed envelopes and will be given to the main researcher for study.
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Babol university of medical sciences
Street address
Daveshjoo 5, keshavarz Blvd.
City
Babol
Province
Mazandaran
Postal code
47176-59964
Approval date
2021-08-31, 1400/06/09
Ethics committee reference number
IR.MUBABOL.REC.1400.216

Health conditions studied

1

Description of health condition studied
Ectopic pregnancy
ICD-10 code
O00.1
ICD-10 code description
Tubal pregnancy

Primary outcomes

1

Description
Anti-Mullerian Hormone level
Timepoint
At the beginning of the study and three months after hysterectomy
Method of measurement
Chemiluminescence method

Secondary outcomes

1

Description
Follicle-stimulating Hormone (FSH) level
Timepoint
At the beginning of the study and three months after hysterectomy
Method of measurement
Chemiluminescence method

2

Description
Number of antral follicles OF ovary
Timepoint

At the beginning of the study and three months after hysterectomy

Method of measurement

Sonography

3

Description

Ovarian volume

Timepoint

At the beginning of the study and three months after hysterectomy

Method of measurement

Sonography

Intervention groups

1

Description

Intervention group: Patients in this group underwent abdominal hysterectomy. After round ligament amputation, the eutrophic ligament was isolated instead of infendibliplovik and the ovary (one or both ovaries) was preserved and then the cardinal ligament and vaginal cuff were isolated according to the routine protocol of arterial and venous surgery. And the uterus and fallopian tubes come out.

Category

Treatment - Surgery

2

Description

Control group: Patients in this group undergo abdominal hysterectomy at the junction of the fallopian tubes and the uterine ligament and the fallopian tubes and ovaries (one or both ovaries and fallopian tubes) are preserved. And the uterus comes out.

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Rohani hospital

Full name of responsible person

Azita Ghanbarpour

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Ganj afrooz Ave.,Keshavarz Blvd.,Babol.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

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https://research.mubabol.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Babol 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

Babol University of Medical Sciences

Full name of responsible person

Mahboobeh Mohammadpour

Position

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
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Azita Ghanbarpour
Position
Assistant Professor
Latest degree
Specialist
Other areas of specialty/work
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Position
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Latest degree
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Other areas of specialty/work
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Yes - There is a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available
Title and more details about the data/document
All procedures performed, including how patients are selected, laboratory procedures and ultrasound, and the procedure performed during surgery and how patients are followed up after the study will be shared.
When the data will become available and for how long
The access period will start one year after the results are published.
To whom data/document is available
Academics, researchers, and students, can access the study.
Under which criteria data/document could be used
All analyzes are performed in order to make better and more use of the research and to upgrade the knowledge and surgical processes.
From where data/document is obtainable
mahboobehmohammadpour@gmail.com
00989111191874
What processes are involved for a request to access data/document
After viewing the email and verifying the identity of the applicant, the data file will be provided.
Comments