Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The effect of selenium and vit E supplementation on anti-mullerian hormone (AMH) index and antral follicle count in infertile women with occult premature ovarian insufficiency: A randomized contorolled clinical trial

Protocol summary

Study aim

• Comparison of AMH concentration 12 months after initiation of intervention in the group receiving selenium and vitamin E and placebo group with control of the effect of AMH concentration before intervention • Comparison of the number of ovarian antral follicles 12 months after intervention in the group receiving selenium and vitamin E and placebo group with control of the effect of number of antral ovarian follicles before intervention • Comparison of ovarian volume 12 months after intervention in the group receiving selenium and vitamin E and placebo group with control of ovarian volume before intervention • Determining the frequency of adverse events in the treatment group for selenium and vitamin E recipients and the placebo group

Design

This is a randomized, controlled triple blinded with two arm parallel group clinical trial that have been designed for Occult POI patients referred to Al-Zahra clinic and clinics and clinics affiliated to Tabriz University of Medical Sciences. . The sample size is 35 in each grou

Settings and conduct

This is a randomized, controlled triple blinded with two arm parallel group clinical trial that have been designed for Occult POI patients referred to Al-Zahra clinic and clinics and clinics affiliated to Tabriz University of Medical Sciences.In this study, the participants and the person who performed the statistical analysis will be blinded

Participants/Inclusion and exclusion criteria

Entry Criteria: Accepting informed written consent Women aged 20 to 40 years old Menstrual cycle Having two ovaries There is no evidence of endocrine disorders (diabetes, thyroid disorders, Addison's disease, etc.) by asking the patient and checking out the results of previous patient tests. Occult POI (hormone AMH <1 ng / ml, reduced ovarian reserve, less than 5 anthral follicles, reduced ovarian volume to less than 2.5 cubic centimeters, or all three cases) With BMI <30, the weight and height in this study will be measured by the researcher and the BMI will be calculated according to the formula below. BMI = (WEIGHT (kg)) / (LENGTH (m ^ 2)) Non-arrival criteria: Drug Addiction and Tobacco Use Tend to use donation eggs Having evidence of OVERT POI (FSH> 15 or amenorrhea for more than 3 months) Supplementation of Selenium and Vitamin E three months before the onset of intervention Having a history of radiotherapy and chemotherapy Taking anticoagulants (co-administration of vitamin E with these drugs increases the risk of bleeding).

Intervention groups

The intervention group will receive Selenium pills and vitamin E for three months.The other group will receive the placebo of these two supplements. Because both (selenium and vitamin E) are the cofactor of the enzyme GPX, there is therefore no need for a separate group to check vitamin E or selenium alone

Main outcome variables

AMH concentration 12 months after intervention؛Number of antral follicles in ovarian 12 months after the intervention؛Volume of ovaries 12 months after intervention؛The incidence of side effects of selenium and vitamin E

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20160410027311N6**
Registration date: **2018-04-30, 1397/02/10**
Registration timing: **prospective**

Last update: **2018-04-30, 1397/02/10**

Update count: **0**

Registration date

2018-04-30, 1397/02/10

Registrant information

Name

Behnaz Sadeghzadeh Oskouei

Name of organization / entity

Tabriz University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 41 3479 0364

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-05-04, 1397/02/14

Expected recruitment end date

2018-09-05, 1397/06/14

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of selenium and vit E supplementation on anti-mullerian hormone (AMH) index and antral follicle count in infertile women with occult premature ovarian insufficiency: A randomized contorolled clinical trial

Public title

The effect of selenium and vit E supplementation on Oogenesis improvement in infertile women with occult premature ovarian insufficiency: A randomized contorolled clinical trial

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Accepting informed written consent Women aged 20 to 40 years old Menstrual cycle Having two ovaries There is no evidence of endocrine disorders (diabetes, thyroid disorders, Addison's disease, etc.) by asking the patient and checking out the results of previous patient tests. Occult POI (hormone AMH <1 ng / ml, reduced ovarian reserve, less than 5 anthral follicles, reduced ovarian volume to less than 2.5 cubic centimeters, or all three cases) With BMI <30, the weight and height in this study will be measured by the researcher and the BMI will be calculated according to the formula below. BMI = (WEIGHT (kg)) / (LENGTH (m ^ 2))

Exclusion criteria:

Drug Addiction and Smoking The tendency to use donated eggs Having evidence of OVERT POI (FSH> 15 or amenorrhea for more than 3 months) Supplementation of selenium and vitamin E three months before the onset of intervention Having a history of radiotherapy and chemotherapy The use of anticoagulants (co-administration of vitamin E with these drugs increases the risk of bleeding)

Age

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

Gender

Female

Phase

N/A

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size

Target sample size: **70**

Randomization (investigator's opinion)

Randomized

Randomization description

Participants will be randomly assigned 1 to 1 using the 4 and 6 block method right before the intervention begins.

Blinding (investigator's opinion)

Triple blinded

Blinding description

Blinding the allocation by a non-trafficker is done in the sampling and the received intervention (drug or placebo) is placed in the numbered blank opaque glasses, thus identifying the placement of the individuals. Glasses will be numbered from 1 to 70. The first person will be given the number one glass, and this will continue until the end of the sampling.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Tabriz University of Medical Sciences

Street address

Azadi St., Golghast St., Tabriz University of Medical Sciences, Central Building No. 2, Third Floor, Research Deputy Directorate

City

Tabriz

Province

East Azarbaijan

Postal code
5166614766
Approval date
2018-03-12, 1396/12/21
Ethics committee reference number
IR.TBZMED.REC.1396.1255

Health conditions studied

1

Description of health condition studied
occult premature ovarian insufficiency
ICD-10 code
E28.3
ICD-10 code description
Primary ovarian failure

Primary outcomes

1

Description
Concentration of anti-mullerian hormone (AMH)
Timepoint
Before the intervention begins and 12 months after the intervention begins
Method of measurement
To monitor the level of anti-mullerian hormone, blood sampling will be performed on the day of referral from the Brachial vein and will be immediately transferred to the laboratory and will be used with an ELISA kit.

2

Description
Number of ovarian antal follicles
Timepoint
Before the intervention begins and 12 months after the intervention begins
Method of measurement
Transvaginal ultrasonography of the ovary on the third day of the menstrual cycle, performed by a radiologist and a device for all participants to check the number of antral follicles.

Secondary outcomes

1

Description
Ovarian volume
Timepoint
Before the intervention begins and 12 months after the intervention begins
Method of measurement
Ovarian volume with the same ultrasound on the third day of menstruation using the following formula Ovarian volume = Length × height × width × π / 6 It will be calculated for each ovary separately

2

Description
The incidence of side effects of selenium and vitamin E and their placebo
Timepoint
After the end of the intervention
Method of measurement
The side effects of medicines will be questioned according to the checklist given during supplements or placebo and will be recorded in the checklist.

Intervention groups

1

Description
Intervention group: The intervention group will receive one tablet of selenium 200 micrograms daily and one vitamin E 400 units per day for 90 days.
Category
Treatment - Drugs

2

Description
Control group: The control group will receive the plasebo of Selenium and vitamin E for 90 days.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Infertility Clinic of Al-Zahra Hospital
Full name of responsible person
Safiyeh Farhadi Dizaji
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tabriz University of Medical Sciences

Full name of responsible person
Dr Mohammadreza Rashidi
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Tabriz University of Medical Sciences, Golghasht St., Azadi St., Central Building No. 2, Third Floor, Department of Research Vice-Chancellery of Tabriz University of Medical Sciences
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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
Tabriz 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
Tabriz University of Medical Sciences
Full name of responsible person
Safiyeh Farhadi Dizaji
Position
Midwifery Masters student
Latest degree
Bachelor
Other areas of specialty/work
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

There is no program for publishing participant data file

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

The results of the clinical study will be published as a article

When the data will become available and for how long

Immediately after publishing the results

To whom data/document is available

All researchers

Under which criteria data/document could be used

Scientific citation based on article

From where data/document is obtainable

email: sadeghzadehb@tbzmed.ac.ir

What processes are involved for a request to access data/document

Up to one week after comunication by email

Comments