

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Jul 2026

The effect of supplementation with Amino selenium on the course of the disease, painful signs and symptoms in women with endometriosis: A triple blind randomized controlled trial

Protocol summary

Study aim

To determine the effect of supplementation with Amino Selenium on the course of the disease, painful symptoms and signs in women with endometriosis

Design

A clinical trial with a control group, parallel group, triple-blind, randomized, phase 3 on 66 patient. The stratified random block method was used for randomization.

Settings and conduct

This study will be conducted on 66 women with endometriosis who have a case file at the Gynecology and Obstetrics Clinic of Al-Zahra Medical Training Center and Sheikh Al-Raees Specialized Clinic in Tabriz. The intervention group will be given organic selenium and the control group will be given placebo capsules. At the beginning of the intervention, the participants will be reminded that the next follow-up will be every month after the start of the intervention for 3 months, so that in the first month, once a week, and in the second and third months, once every two weeks, the participants will be contacted by phone and consumed the drug or placebo will be reminded and they will be asked to check the drug consumption checklist.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Women with symptomatic endometriosis
Exclusion criteria: Definite need for surgery based on the opinion of obstetrician and gynecologist

Intervention groups

In this study, one group will receive amino selenium as the intervention groups and for the control group will receive placebo daily for three months. Both groups will be given routine treatment (Verogest 2 mg once a day for six months).

Main outcome variables

Average endometrioma cyst size 3 months after starting the treatment

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20110606006709N26**

Registration date: **2023-12-30, 1402/10/09**

Registration timing: **prospective**

Last update: **2023-12-30, 1402/10/09**

Update count: **0**

Registration date

2023-12-30, 1402/10/09

Registrant information

Name

Mahnaz Shahnazi

Name of organization / entity

Tabriz University of Medical Science

Country

Iran (Islamic Republic of)

Phone

+98 41 1479 6770

Email address

mshahnazi@tbzmed.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-01-19, 1402/10/29

Expected recruitment end date

2024-06-18, 1403/03/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty		selenium and placebo will be prepared by Tabriz nutrition research center in a completely similar way in terms of appearance and; the usage method will be the same. Blocking will be done by a person not involved in sampling. In order to concealment allocation, drugs and placebo will be placed in completely identical falcons randomly and allocated by a person not involved in the study, which will be consecutively numbered from 1 to 66.	
Scientific title		Placebo	
The effect of supplementation with Amino selenium on the course of the disease, painful signs and symptoms in women with endometriosis: A triple blind randomized controlled trial		Used	
Public title		Assignment	
Investigating the effect of amino selenium in the treatment of endometriosis		Parallel	
Purpose		Other design features	
Treatment			
Inclusion/Exclusion criteria		Secondary Ids	
Inclusion criteria:		empty	
Women of reproductive age (15-49 years) Being literate in reading and writing Women with primary endometriosis with endometrioma less than 5 cm Women with symptomatic endometriosis (dysmenorrhoea pain score of 16 or more in the Mous Menstrual Distress Questionnaire) Married women who are sexually active		Ethics committees	
Exclusion criteria:		1	
Probability of malignancy based on vaginal ultrasound Definite need for surgery based on the opinion of obstetrician and gynecologist Suffering from diseases such as myoma or hyperplasia or polycystic ovary syndrome based on vaginal ultrasound Daily and regular consumption of supplements containing Amino Selenium during the last three months according to the patient's statement Suffering from liver and kidney diseases and the need for dialysis Pregnancy and breastfeeding Desire to get pregnant in the next trimester Allergy to Gelofen		Ethics committee	
Age		Name of ethics committee	
From 15 years old to 49 years old		Ethics Committee of Tabriz University of Medical Sciences	
Gender		Street address	
Female		Reaserch department, third floor, central construction number 2, Tabriz university of medical sciences, Golgasht street, Azadi avenue	
Phase		City	
3		Tabriz	
Groups that have been masked		Province	
- Participant - Care provider - Investigator - Data analyser		East Azarbaijan	
Sample size		Postal code	
Target sample size: 66		5138947977	
Randomization (investigator's opinion)		Approval date	
Randomized		2023-12-18, 1402/09/27	
Randomization description		Ethics committee reference number	
The participants will be randomly chassified by the block method with a block size of four and six and a ratio of 1:1 allocation in tow intervention (Amino selenium) and control (placebo) groups. A person from research team not involved in the recruitment and assigning participants will generate allocation sequence using a computerized program.		IR.TBZMED.REC.1402.570	
Blinding (investigator's opinion)		Health conditions studied	
Triple blinded		1	
Blinding description		Description of health condition studied	
People involved in sample selection, data collection, analysis and the participants will be blinded. Amino		Endometriosis	
		ICD-10 code	
		N80	
		ICD-10 code description	
		Endometriosis	
		Primary outcomes	
		1	
		Description	
		Average endometrioma cyst size	
		Timepoint	
		Before the intervention and 3 months after the start of intervention	

Method of measurement

Vaginal ultrasound

2**Description**

Average dysmenorrhea score

Timepoint

Monthly during 3 months (1, 2, 3 months) after the start of the intervention

Method of measurement

Mous Menstrual Distress Questionnaire (MMDQ)

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

Average dyspareunia score

Timepoint

Monthly during 3 months (1, 2, 3 months) after the start of the intervention

Method of measurement

Visual analog scale (VAS)

2**Description**

Average score of dysuria

Timepoint

Monthly during 3 months (1, 2, 3 months) after the start of the intervention

Method of measurement

Visual analog scale (VAS)

3**Description**

Average score of Dyschezia

Timepoint

Monthly during 3 months (1, 2, 3 months) after the start of the intervention

Method of measurement

Visual analog scale (VAS)

4**Description**

Average score of non cyclic pain

Timepoint

Monthly during 3 months (1, 2, 3 months) after the start of the intervention

Method of measurement

Visual analog scale (VAS)

Intervention groups**1****Description**

Intervention group: A 250 mg capsule containing 200 µg of amino selenium enriched with Saccharomyces

cerevisiae yeast was made at the Tabriz Nutrition Research Center and will be used once a day for 3 months.

Category

Treatment - Drugs

2**Description**

Control group: A 250 mg capsule containing Saccharomyces cerevisiae yeast was made at the Tabriz Nutrition Research Center and one capsule will be used daily for 3 months.

Category

Placebo

Recruitment centers**1****Recruitment center****Name of recruitment center**

Al-Zahra educational hospital

Full name of responsible person

Mahnaz Shahnazi

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Alzahra Hospital, Artesh street

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

Sheykh Al-Rais clinic

Full name of responsible person

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Dr Parviz Shahabi

Street address

Research department, third floor, central construction
number 2, Tabriz University of Medical Sciences,
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Web page address**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

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Person responsible for scientific inquiries

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Full name of responsible person

Mahnaz Shahnazi

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

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Person responsible for general inquiries

Contact**Name of organization / entity**

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Full name of responsible person

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Position

Student of master's degree in Midwifery

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

Confidentiality of participants' information

Study Protocol

No - There is not 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

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