

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 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	Placebo Used
Public title Investigating the effect of amino selenium in the treatment of endometriosis	Assignment Parallel
Purpose Treatment	Other design features
Inclusion/Exclusion criteria Inclusion criteria: 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 Exclusion criteria: 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	Secondary Ids empty
Age From 15 years old to 49 years old	Ethics committees 1 Ethics committee Name of ethics committee Ethics Committee of Tabriz University of Medical Sciences Street address Reaserch department, third floor, central construction number 2, Tabriz university of medical sciences, Golgasht street, Azadi avenue City Tabriz Province East Azarbaijan Postal code 5138947977
Gender Female	Approval date 2023-12-18, 1402/09/27
Phase 3	Ethics committee reference number IR.TBZMED.REC.1402.570
Groups that have been masked - Participant - Care provider - Investigator - Data analyser	Health conditions studied 1 Description of health condition studied Endometriosis ICD-10 code N80 ICD-10 code description Endometriosis
Sample size Target sample size: 66	Primary outcomes 1 Description Average endometrioma cyst size
Randomization (investigator's opinion) Randomized	Timepoint Before the intervention and 3 months after the start of intervention
Randomization description 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.	
Blinding (investigator's opinion) Triple blinded	
Blinding description People involved in sample selection, data collection, analysis and the participants will be blinded. Amino	

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

Street address

Alzahra Hospital, Artesh street

City

Tabriz

Province

East Azarbaijan

Postal code

5138947977

Phone

+98 41 3479 6770

Email

nursing@tbzmed.ac.ir

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

Sheykh Al-Rais clinic

Full name of responsible person

Mahnaz Shahnazi

Street address

Sheikhalrayis clinic, Azadi street

City

Tabriz

Province

East Azarbaijan

Postal code

5167846184

Phone

+98 41 3336 6215

Email

mshahnazi@tbzmed.ac.ir

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,
Golgashat Street, Azadi Avenue, Tabriz

City

Tabriz

Province

East Azarbaijan

Postal code

5138947977

Phone

+98 41 3335 7310

Fax

+98 41 1334 4280

Email

iro@tbzmed.ac.ir

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

Postal code

5415933739

Phone

+98 41 3475 3906

Fax

+98 41 3475 3906

Email

ftmf.97@gmail.com

Web page address

<http://nursing.tbzmed.ac.ir>

Person responsible for scientific inquiries

Contact

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Mahnaz Shahnazi

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Midwifery

Street address

Faculty of Nursing and Midwifery, South Shariati
Street

City

Tabriz

Province

East Azarbaijan

Postal code

5138947977

Phone

+98 41 3477 2699

Fax

+98 41 3479 6969

Email

mshahnazi@tbzmed.ac.ir

Web page address

<http://nursing.tbzmed.ac.ir>

Person responsible for general inquiries

Contact

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Fatemeh Teihoomanesh fard

Position

Student of master's degree in Midwifery

Latest degree

Bachelor

Other areas of specialty/work

Midwifery

Street address

Faculty of Nursing and Midwifery, South Shariati
Street

City

Tabriz

Province

East Azarbaijan

Person responsible for updating data

Contact

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Fatemeh Teihoomanesh fard

Position

Student of master's degree in Tabriz

Latest degree

Bachelor

Other areas of specialty/work

Midwifery

Street address

Faculty of Nursing and Midwifery, South Shariati
Street

City

Tabriz

Province

East Azarbaijan

Postal code

5415933739

Phone

009841344753906

Fax

+98 41 3479 6969

Email

ftmf.97@gmail.com

Web page address

<http://nursing.tbzmed.ac.ir>

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