

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

Effects of vitamin E and C supplements on serum levels of biomarkers of oxidative stress and pelvic pain in women with endometriosis symptoms

Protocol summary

Summary

Objectives: To determine the serum levels of oxidative stress biomarkers (TAC-ROS-MDA) and pelvic pain in intervention and placebo groups. Design: Thirty women at age 49-15 years old, married, with clinical symptoms of endometriosis participate in each group. This study is randomized and triple-blind sampling. Criteria: Patients who not receive any supplementation in the last six month and without any pelvic inflammatory disease history. The exclusion criteria are unwillingness of the patient and pregnancy. Intervention: Patients have a random number from 1 to 60 and then persons divide two groups (odd and even). All patients fill the questionnaire form and 10 ml blood collect from them to measure serum level of oxidative stress biomarkers and Vit E vitamin E Before the intervention at Sarem Hospital Research Center. Patients receive vitamin E (400 units) twice daily (800 IU) and vitamin C tablets 500 mg twice daily (1000 mg) for eight week duration. They dived two groups (A and B) and after 8 weeks second blood samples collect. The questionnaire visual analogue scale (VAS) form fill by volunteers before, every 2 weeks and in final. Main outcome measures: Primary variable outcome is oxidative stress biomarkers that measure before and two month after intervention. Secondary outcome variable is pelvic pain that evaluate 2 weeks by visual analogue scale instruments.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201106296917N1**
Registration date: **2015-10-12, 1394/07/20**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2015-10-12, 1394/07/20

Registrant information

Name

Leila Amini

Name of organization / entity

Tehran University of Medical Science

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Recruitment status

Recruitment complete

Funding source

Research Unit, School of Nursing and Midwifery, Iran;
Cellular and Molecular Sciences of Sarim Hospital

Expected recruitment start date

2015-06-21, 1394/03/31

Expected recruitment end date

2016-02-19, 1394/11/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effects of vitamin E and C supplements on serum levels of biomarkers of oxidative stress and pelvic pain in women with endometriosis symptoms

Public title

The impact of vitamins and antioxidants on the severity of endometriosis, pelvic pain in women

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: No current infection or a history of pelvic inflammatory disease during the study; Adenomyosis of disease, lack of supplementation in the last six months, not smoking, alcohol, lack of underlying chronic disease or mental illness known to his remarks patient, not a specific diet) such as a vegetarian diet); women with dysmenorrhea, irregular menstruation, lack of passing clots during menstruation. Exclusion criteria from the study: The patient's unwillingness to continue the research, side effects and drug allergy (such as fatigue, headache, blurred vision, nausea, diarrhea), the occurrence of pregnancy, diagnosed in the laparoscopy Adenomyosis

Age

From **15 years** old to **45 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size:

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Triple blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

By random method of packaging the door closed, that even numbers in a group and odd numbers in another group.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Iran University of Medical Sciences

Street address

Iran University of Medical Sciences, Intersection of Sheikh Fazlollah Nouri and Shahid Chamran, Shahid Hemat Highway

City

Tehran

Postal code

Approval date

2015-04-04, 1394/01/15

Ethics committee reference number

19/ 105/ 94 / 3

Health conditions studied

1

Description of health condition studied

endometriosis

ICD-10 code

n80

ICD-10 code description

n80.9

Primary outcomes

1

Description

Bio-markers of oxidative stress

Timepoint

Two months before the intervention and after intervention

Method of measurement

Biomarker of oxidative stress in vitro assay kit

Secondary outcomes

1

Description

Severe pelvic pain

Timepoint

bi-weekly

Method of measurement

Visual analogue instruments

Intervention groups

1

Description

Intervention group 1: In this study, the purpose of oral administration of vitamin E 800 units (two tablets of 400 IU) twice a day for 8 weeks and vitamin c tablets a day to 1000 mg (4 tablets of 250 mg) 4 times day for 8 weeks.

Category

Placebo

2

Description

Control group: Taking 2 pills placebo vitamin E (400 IU) and 800 units of 4 placebo vitamin C (250 mg), a total of 1000 mg daily for 8 weeks.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Women Clinic of Sarem Hospital

Full name of responsible person

Dr. Arash Poladi Research Assistant Department of Cellular and Molecular Sarem Hospital

Street address

Women Clinic of Sarem Hospital, Shahrak Ekbatan, Azadi Square

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran University of Medical Sciences- Sarem Hospital

Full name of responsible person

Vice Chancellor for research of Sarem Hospital

Street address

Research Section of Sarem Hospital, Shahrak Ekbatan, Azadi Square

City

Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Iran University of Medical Sciences- Sarem Hospital

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Iran University of Medical Sciences, School of Nursing and Midwifery

Full name of responsible person

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Position

Master of Midwifery

Other areas of specialty/work

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Person responsible for scientific inquiries

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty