

Clinical Trial Protocol

Iranian Registry of Clinical Trials

31 May 2026

Effect of oral administration of N- acetyl cysteine on decrease of oxidative stress , Concentration of heavy metals and lipid profile in Women with Endometriosis

Protocol summary

Study aim

Evaluation of oral N-acetylcysteine administration on reduction of oxidative stress, heavy metal concentration and serum lipid profile in women with endometriosis

Design

This is a parallel, non-blinded, randomized controlled clinical trial

Settings and conduct

this study will be done at the Fatemehzahra Infertility Center of Babol University of Medical Sciences. Sixty women with endometriosis will be divided into two groups (30 in each group), intervention group will be received routine treatment with n-acetylcysteine and comparison group received routine treatment. Index of lipid peroxidation, total antioxidant capacity and carbonyl will be measured. Determination of iron and lactate dehydrogenase in blood samples of patients by spectrophotometric method and determination of 8-hydroxy-2-deoxy guanosine as an indicator of DNA oxidative stress by ELISA and heavy metals by atomic absorption and lipid indices Spectrophotometry will be performed.

Participants/Inclusion and exclusion criteria

Endometriosis, 20-45 years old, not taking antioxidants and non-clinical, or surgical treatment in the past 6 months, no chronic diseases such as: hepatitis, thalassemia anemia, diabetes , infectious diseases and Inflammatory.

Intervention groups

The experimental group will receive routine treatment and a 6-week oral administration of N-acetylcysteine at a daily dose of 8.1 g daily (3 g daily for obese women). The control group will receive only routine treatment.

Main outcome variables

Malondialdehyde, lactate dehydrogenase, total antioxidant capacity, zinc, copper, lead, cadmium, nickel, chromium and lipid indices.

General information

Reason for update

Modification of sample age and incorrect typing correction

Acronym

IRCT registration information

IRCT registration number: **IRCT20100411003684N9**

Registration date: **2020-01-27, 1398/11/07**

Registration timing: **registered_while_recruiting**

Last update: **2020-05-16, 1399/02/27**

Update count: **1**

Registration date

2020-01-27, 1398/11/07

Registrant information

Name

Soleiman Mahjoub

Name of organization / entity

Babol University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Vice-Chancellor for research of Babol University of Medical Sciences

Expected recruitment start date

2019-09-22, 1398/06/31

Expected recruitment end date

2020-09-21, 1399/06/31

Actual recruitment start date

empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Effect of oral administration of N- acetyl cysteine on decrease of oxidative stress , Concentration of heavy metals and lipid profile in Women with Endometriosis

Public title
Effect of oral administration of N- acetyl cysteine in Women with Endometriosis

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Women with endometriosis Age 20-35 years old
Laparoscopic diagnosis of endometriosis Not taking antioxidant supplements Lack of chronic diseases such as: diabetes- hepatitis- thalassemia anemia-infectious and inflammatory diseases No clinical or surgical treatment for the past six months Lack of polycystic ovary

Exclusion criteria:
Non-use of medication Thalassemia. Diabetes- Hepatitis- Anemia-Infectious and Inflammatory diseases.

Age
From **20 years** old to **35 years** old

Gender
Female

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
Simple randomization

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
University of Medical Sciences , Ganjafrooz Street , Babol , Mazandaran ,Iran
City
Babol
Province
Tehran
Postal code
47176-47745
Approval date
2012-12-09, 1391/09/19
Ethics committee reference number
MUBABOL.HRI.REC.1393.1671

Health conditions studied

1

Description of health condition studied
Endometriosis
ICD-10 code
N80.8
ICD-10 code description
Other endometriosis

Primary outcomes

1

Description
Malondialdehyde (MDA)
Timepoint
6 Weeks
Method of measurement
TBARS Method (Spectrophotometry)

2

Description
Total antioxidant capacity (TAC)
Timepoint
6 Weeks
Method of measurement
FRAP Method

3

Description
Blood Iron
Timepoint
6 Weeks
Method of measurement
Spectrophotometry

4

Description
Lactate dehydrogenase (LDH)
Timepoint
6 Weeks
Method of measurement

Spectrophotometry

5

Description

8-OH-2-deoxy-Guanosine (8-OHdG)

Timepoint

6 Weeks

Method of measurement

ELISA

6

Description

Carbonyl

Timepoint

6 Weeks

Method of measurement

Levin Method

7

Description

DPPH index

Timepoint

6 Weeks

Method of measurement

Spectrophotometry

Secondary outcomes

1

Description

Levels of Lead

Timepoint

6 week

Method of measurement

Atomic absorption

2

Description

Levels of cadmium

Timepoint

6 Week

Method of measurement

Atomic absorption

3

Description

Levels of nickel

Timepoint

6 Week

Method of measurement

Atomic absorption

4

Description

Levels of chromium

Timepoint

6 Week

Method of measurement

Atomic absorption

5

Description

Levels of High Density Lipoprotein (HDL)

Timepoint

6 Week

Method of measurement

Spectrophotometer

6

Description

Levels of Low Density Lipoprotein (LDL)

Timepoint

6 Week

Method of measurement

Spectrophotometer

7

Description

Levels of Triglyceride

Timepoint

6 Week

Method of measurement

Spectrophotometer

8

Description

Levels of Cholesterol

Timepoint

6 Week

Method of measurement

Spectrophotometer

9

Description

Levels of Cu

Timepoint

6 Week

Method of measurement

Spectrophotometer

10

Description

Levels of Zn

Timepoint

6 Week

Method of measurement

Spectrophotometer

11

Description

Levels of Zn

Timepoint

6 Week

Method of measurement

Spectrophotometer

12**Description**

Level of Carbonyl

Timepoint

6 Week

Method of measurement

Spectrophotometer

13**Description**

DPPH Index

Timepoint

6 Week

Method of measurement

Spectrophotometer

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

Oral administration of N- acetyl cysteine with dose of 1/8 gr/day (overweight women 3 gr/day) during 6 weeks in addition to routine medication in women with endometriosis.

Category

Treatment - Drugs

2**Description**

The control group will be received routine medication.

Category

Treatment - Drugs

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

Infertility and Reproductive Health Research Center

Full name of responsible person

Dr Sadighe Esmaeilzadeh

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Infertility and Reproductive Health Research Center,
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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Babol University of Medical Sciences

Full name of responsible person

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Grant name**Grant code / Reference number**

913438

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

Prof. Soleiman Mahjoub

Position

Academic member

Latest degree

Ph.D.

Other areas of specialty/work

Biochemistry

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Person responsible for updating data

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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

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

Data on the main outcome will be available

When the data will become available and for how long

Six months after the publication of result

To whom data/document is available

Researchers working in academic and scientific institutions

Under which criteria data/document could be used

It is not yet known

From where data/document is obtainable

professor Soleiman Mahjoub smahjoub20@yahoo.com
OR s.mahjoub@mubabol.ac.ir

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

Two weeks after application

Comments