Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Eeffect 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 Fatemezahra 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-doxy 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)

Phone
+98 11 3219 0569

Email address
s.mahjoub@mubabol.ac.ir

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

Eeffect 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

Eeffect 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
Street address
Infertility and Reproductive Health Research Center, Fatemeh Zahra Hospital, Babol, Iran
City
Babol
Province
Mazandaran
Postal code
47176-47745
Phone
+98 11 3227 4882
Email
sesmael2010@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Babol University of Medical Sciences
Full name of responsible person
Dr Reza Ghadimi
Street address
University of Medical Sciences , Ganjafrooz Street , Babol , Mazandaran ,Iran
City
Babol
Province
Mazandaran
Postal code
47176-47745
Phone
+98 11 3219 0557
Email
rezaghadimi@yahoo.com
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
Street address
University of Medical Sciences , Ganjafrooz Street , Babol , Mazandaran ,Iran
City
Babol
Province
Mazandaran

Postal code
47176-47745
Phone
+98 11 3219 0569
Fax
Email
smahjoub20@gmail.com
Web page address

Person responsible for scientific 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
Street address
Department of Biochemistry, Babol University of Medical Sciences, Babol
City
Babol
Province
Mazandaran
Postal code
47176-47745
Phone
+98 11 1219 0569
Fax
Email
s.mahjoub@mubabol.ac.ir
Web page address
https://www.researchgate.net/profile/Prof_Dr_Soleiman_Mahjoub2/?ev=hdr_xprf

Person responsible for updating data

Contact
Name of organization / entity
Babol University of Medical Sciences
Full name of responsible person
Prof. Soleiman Mahjoub
Position
Ph.D.
Latest degree
Ph.D.
Other areas of specialty/work
Biochemistry
Street address
Department of Biochemistry , Babol University of Medical Sciences
City
Babol
Province
Mazandaran
Postal code
47176-47745
Phone
+98 11 3219 0569
Fax
+98 11 3219 0569
Email
smahjoub20@yahoo.com
Web page address

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