

# 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-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**  
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

**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](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