Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Effectiveness of N-acetyl cysteine(NAC) and vitamin C in patients with endometriosis

Protocol summary

Study aim
effectiveness of NAC & vitamin C in patients with endometriosis

Design
The clinical trial has 3 parallel intervention groups, randomized, phase 2 on 48 patients

Settings and conduct
Sampling will be done at Rasool Akram Hospital affiliated to Iran University of Medical Sciences. Patients are divided into 3 groups. The target sample is blood and the volume of blood used to perform this test is 5 ml. The first intervention group (group I) is given vitamin C, the second intervention group (group II) is given N-acetylcysteine, and the third intervention group (group III) is given a combination of N-acetylcysteine and vitamin C.

Participants/Inclusion and exclusion criteria
Inclusion criteria: • Age group 18-35 years • not menopause • diagnosis of endometriosis in the last 10 years • pain score 6-7 • Resistance to previous treatments • Written consent of the patient Exclusion criteria: • History of chronic pelvic pain that was not due to endometriosis. • History of autoimmune, cardiovascular & kidney diseases •Abnormal liver enzymes • History of osteoporosis • History of other metabolic diseases including DM, HLP &metabolic syndrome • Simultaneous reception of steroid hormones and doses and GnRH analogues and systemic glucocorticoids in the last 3 months • Lack of patient satisfaction

Intervention groups
3 groups

Main outcome variables
intensity of pain Interleukin 6 TNFα Abdominal and pelvic ultrasound findings

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20220817055727N2**
Registration date: **2023-07-28, 1402/05/06**
Registration timing: **prospective**

Last update: **2023-07-28, 1402/05/06**
Update count: **0**

Registration date
2023-07-28, 1402/05/06

Registrant information

Name
Shahla Chaichian

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 21 6650 9283

Email address
shchaichian@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-09-23, 1402/07/01

Expected recruitment end date
2024-09-22, 1403/07/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Effectiveness of N-acetyl cysteine(NAC) and vitamin C in patients with endometriosis

Public title
Effectiveness of N-acetyl cysteine(NAC) and vitamin C in patients with endometriosis
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
Age group 18-35 years old • No menopause • Definitive diagnosis of endometriosis in the last 10 years • Experience of moderate to severe pain (pain score 6-7) • Patients who have resisted common endometriosis treatments or did not respond well to previous treatments. • Written patient consent.
Exclusion criteria:
history of chronic pelvic pain that was not due to endometriosis. History of autoimmune, cardiovascular and kidney diseases according to the patient. Abnormal liver enzymes. History of osteoporosis according to the patient. History of other metabolic diseases, including diabetes, dyslipidemia, and metabolic syndrome according to his tests • Simultaneous reception of steroid hormones in different pharmaceutical forms and various doses in the last 3 months • Simultaneous reception of GnRH analogs in the last 3 months • Simultaneous reception of systemic glucocorticoids in the last 3 months • Lack of patient satisfaction
Age
From **18 years** old to **35 years** old
Gender
Female

Phase
2
Groups that have been masked
No information
Sample size
Target sample size: **48**
Randomization (investigator's opinion)
N/A
Randomization description
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
Research Ethics Committees of Tehran Islamic Azad University Of Medical Sciences
Street address
13th floor, Block A, Ministry of Health, Treatment and Medical Education headquarters, Simaye Iran St, between South Flamak and Zarafshan, Quds settlement (Gharb), Tehran
City
tehran
Province
Tehran
Postal code
1467664961
Approval date
2023-04-17, 1402/01/28
Ethics committee reference number
IR.IAU.TMU.REC.1402.033

Health conditions studied

1

Description of health condition studied
Endometriosis
ICD-10 code
N80.9
ICD-10 code description
Endometriosis, unspecified

Primary outcomes

1

Description
Intensity of pain
Timepoint
Before and 12 weeks after treatment
Method of measurement
Vas score questionnaire

2

Description
Interleukin-6
Timepoint
Before and 12 weeks after treatment
Method of measurement
ELISA reader device

3

Description
TNFα
Timepoint
Before and 12 weeks after treatment
Method of measurement
ELISA reader device

4

Description
Abdominal and pelvic ultrasound findings
Timepoint
Before and 12 weeks after treatment
Method of measurement
Ultrasound device

Secondary outcomes

empty

Intervention groups

1

Description
In this study, people are divided into 3 intervention groups; Before and 12 weeks after the treatment, with the patient's consent, the serum levels of IL-6 and TNFα are checked with an ELISA device, ultrasound of the abdomen and pelvis to detect endometriosis lesions, as well as pain intensity using the VAS questionnaire.
Category
Treatment - Drugs

2

Description
Intervention group: The first intervention group (group I) is given vitamin C (1000 mg per day).
Category
Treatment - Drugs

3

Description
Intervention group: The second intervention group (group II) is given N-acetylcysteine (600 mg per day).
Category
Treatment - Drugs

4

Description
Intervention group: The third intervention group (group III) is given a combination of N-acetylcysteine (600 mg per day) and vitamin C (1000 mg per day).
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Hazrat-e- Rasool hospital
Full name of responsible person
Dr.Shahla Chaichian
Street address
Rasool-e Akram Hospital, Niayesh St., Sttarkhan St., Tehran, Iran
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1445613131
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Rasoolhospital@iums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Islamic Azad University
Full name of responsible person
shahla chaichian
Street address
Headquarters Building of Tehran Islamic Azad University of Medical Sciences, Corner of Gol Yakh St., Ayane Blvd., Amir Pabarja St., Qolhek Road, Doktor Shariati St., Tehran
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shchaichian@gmail.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Islamic Azad University
Proportion provided by this source
100
Public or private sector
Private
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Other

Person responsible for general inquiries

Contact
Name of organization / entity
Islamic Azad University
Full name of responsible person
Dr.Shahla Chaichian
Position
Professor
Latest degree
Subspecialist
Other areas of specialty/work
Gynecology and Obstetrics
Street address
Headquarters Building of Tehran Islamic Azad University of Medical Sciences, Corner of Gol Yakh St.,

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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
Yes - There is a plan to make this available

Data Dictionary
Not applicable

Title and more details about the data/document
Part of data like the main outcome or the same will be shared.

When the data will become available and for how long
Access after 6 months after publication

To whom data/document is available
Data will be available for all researchers.

Under which criteria data/document could be used
It is important for further research and identification of markers in reducing patients' pain that can be used later in the pharmaceutical industry.

From where data/document is obtainable
For receiving data please be contacted with shchaichian@gmail.com.

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

Comments