

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Jul 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 TNF α 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)

Phone

+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

TNF α

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 TNF α 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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Postal code

1445613131

Phone

+98 21 6650 9283

Email

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

City

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1949635881

Phone

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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 scientific inquiries

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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