Clinical Trial Protocol
Iranian Registry of Clinical Trials

02 Jun 2026

Effect of N-acetyl cysteine supplementation versus placebo on clinical outcomes in women with chronic pelvic pain syndrome: a double-blind randomized clinical trial

Protocol summary

Study aim
To assess the effect of N-acetyl cysteine supplementation versus placebo on clinical outcomes in women with chronic pelvic pain syndrome

Design
This is a double-blind randomized clinical trial, in which 60 eligible patients will be randomly assigned to the intervention and control groups

Settings and conduct
The eligible women with chronic pelvic pain syndrome referring to the Shahid Beheshti Hospital in Hamadan city during the study period will be enrolled in the trial and will be randomly assigned to the intervention and control groups through the block randomization. This trial will be double-blinded so that neither patients nor the physician examining the patients will be aware of the intervention.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Age of 18 to 50 years, Women with chronic pelvic pain syndrome for at least 6 months, Exclusion criteria: Presence of pathologic or infamous reason for chronic pelvic pain, Mild symptoms (the score less than 15 based on NIH-CPSI questionnaire), Chronic liver or renal disease, Kidney stone or urogenital tract infection, History of surgery of urogenital tract, Contraindication of N-acetyl cysteine

Intervention groups
Intervention group: Amitriptyline 25 mg daily plus N-acetylcysteine tablets (manufactured by Osweh Pharmaceutical Co., Tehran, Iran) 600 mg every 12 hours for 2 months Control group: Amitriptyline 25 mg daily plus placebo tablets (manufactured by Shahid Beheshti School of Pharmacy) every 12 hours for 2 months

Main outcome variables
Primary outcome: Clinical symptoms

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20120215009014N376**
Registration date: **2021-01-22, 1399/11/03**
Registration timing: **prospective**

Last update: **2021-01-22, 1399/11/03**
Update count: **0**

Registration date
2021-01-22, 1399/11/03

Registrant information

Name
Jalal Poorolajal
Name of organization / entity
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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-04-21, 1400/02/01

Expected recruitment end date
2021-11-21, 1400/08/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Effect of N-acetyl cysteine supplementation versus placebo on clinical outcomes in women with chronic pelvic pain syndrome: a double-blind randomized clinical trial

Public title
Effect of N-acetyl cysteine supplementation versus placebo on clinical outcomes in women with chronic pelvic pain syndrome

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Age of 18 to 50 years, Women with chronic pelvic pain syndrome for at least 6 months,

Exclusion criteria:
Presence of pathologic or infamous reason for chronic pelvic pain, Mild symptoms (the score less than 15 based on NIH-CPSI questionnaire), Chronic liver or renal disease, Kidney stone or urogenital tract infection, History of surgery of urogenital tract, Contraindication of N-acetyl cysteine

Age
From **18 years** old to **50 years** old

Gender
Female

Phase
3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
The patients will be randomly assigned to intervention and control groups using block randomization. For this purpose, we will prepare four sheets of paper, writing on two sheets the name of the intervention and on the other two sheets the name of the control. The paper sheets will be pooled, placed in a container, and randomly drawn one at a time for each patient without replacement until all four sheets are drawn. The four paper sheets will be then placed back into the container, and this action repeated until the sample size is reached.

Blinding (investigator's opinion)
Double blinded

Blinding description
The shape of the medications and placebos will be perfectly the same. Therefore, patients will be unaware of the type of intervention. The physician who will examine the patients will not be aware of the intervention. Thus, the trial will be run as triple-blind

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Hamadan University of Medical Sciences

Street address
Vice-chancellor for Research and Technology, Hamadan University of Medical Sciences, Shahid Fahmideh Ave

City
Hamadan

Province
Hamadan

Postal code
6517838695

Approval date
2020-10-24, 1399/08/03

Ethics committee reference number
IR.UMSHA.REC.1399.629

Health conditions studied

1

Description of health condition studied
Chronic pelvic pain syndrome

ICD-10 code
R10.2

ICD-10 code description
Pelvic and perineal pain

Primary outcomes

1

Description
Clinical symptoms

Timepoint
Before the intervention and 4 and 8 weeks after that

Method of measurement
Using the National Institutes of Health - Chronic Prostatitis Symptom Index (NIH-CPSI) standard questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Amitriptyline 25 mg daily plus N-acetyl cysteine tablets (manufactured by Osweh Pharmaceutical Co., Tehran, Iran) 600 mg every 12 hours for 2 months
Category
Treatment - Drugs

2

Description
Control group: Amitriptyline 25 mg daily plus placebo tablets (manufactured by Shahid Beheshti School of Pharmacy) every 12 hours for 2 months
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Shahid Beheshti Hospital in Hamadan city
Full name of responsible person
Somayeh Rahymy
Street address
Shahid Beheshti Hospital, Eram Ave.
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Hamedan University of Medical Sciences
Full name of responsible person
Dr. Saeid Bashirian
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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
Hamedan 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
Hamedan University of Medical Sciences
Full name of responsible person
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Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

Dr. Jalal Poorolajal

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Professor of Epidemiology

Latest degree

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Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available