Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Effect of N-acetyl Cysteine versus placebo as adjunct therapy on the clinical outcomes in patients with chronic non-bacterial prostatitis: a double-blind randomized clinical trial

Protocol summary

Study aim

To assess the effect of N-acetyl Cysteine versus placebo as adjunct therapy on the clinical outcomes in patients with chronic non-bacterial prostatitis

Design

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

Settings and conduct

The eligible patients with chronic non-bacterial prostatitis who will refer to 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.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age of 20 to 40 years, Chronic non-bacterial prostatitis for at least 6 months, The severity of the clinical symptoms at least 15 based on the NIH-CPSI questionnaire Exclusion criteria: Taking anti-androgen medications in the past 6 months, Taking alpha-blockers or other antibiotics in the past month, Taking antioxidant or anti-inflammatory or corticosteroids medications in the past month, Genitourinary tract infection in the past 6 months, Other diseases of the genitourinary system, History of genitourinary system surgery, Chronic liver or kidney disease

Intervention groups

Intervention group: Tamsulosin tablets 0.4 mg (manufactured by Reihana Pharmaceutical Company) daily plus N-acetyl Cysteine tablets 600 mg (manufactured Ave Sina Pharmaceutical Company) every 12 hours for one month Control group: Tamsulosin tablets 0.4 mg (manufactured by Reihana Pharmaceutical Company) daily plus placebo tablets (manufactured by the laboratory of the School of Pharmacy, Hamadan University of Medical Sciences) every 12 hours for one month

Main outcome variables

Primary outcome: The patient's clinical outcome, the severity of pain, the quality of urination

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20120215009014N318**
Registration date: **2019-12-03, 1398/09/12**
Registration timing: **prospective**

Last update: **2019-12-03, 1398/09/12**
Update count: **0**

Registration date

2019-12-03, 1398/09/12

Registrant information

Name

Jalal Poorolajal

Name of organization / entity

Department of Epidemiology & Biostatistics Hamadan University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-12-22, 1398/10/01

Expected recruitment end date

2020-12-21, 1399/10/01

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Effect of N-acetyl Cysteine versus placebo as adjunct therapy on the clinical outcomes in patients with chronic non-bacterial prostatitis: a double-blind randomized clinical trial

Public title
Effect of N-acetyl Cysteine versus placebo as adjunct therapy on the clinical outcomes in patients with chronic non-bacterial prostatitis
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Age of 20 to 40 years, Chronic non-bacterial prostatitis for at least 6 months, The severity of the clinical symptoms at least 15 based on the NIH-CPSI questionnaire
Exclusion criteria:
Taking anti-androgen medications in the past 6 months, Taking alpha-blockers or other antibiotics in the past month, Taking antioxidant or anti-inflammatory or corticosteroids medications in the past month, Genitourinary tract infection in the past 6 months, Other diseases of the genitourinary system, History of genitourinary system surgery, Chronic liver or kidney disease
Age
From **20 years** old to **40 years** old
Gender
Male

Phase
2
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 double-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
2019-11-23, 1398/09/02
Ethics committee reference number
IR.UMSHA.REC.1398.693

Health conditions studied

1

Description of health condition studied
Non-bacterial prostatitis
ICD-10 code
N41.1
ICD-10 code description
Chronic prostatitis

Primary outcomes

1

Description
The patient's clinical outcome
Timepoint
One, two, and three months after the intervention
Method of measurement
by using NIH-CPSI standard questionnaire

2

Description
The severity of pain
Timepoint
One, two, and three months after the intervention
Method of measurement
By using Visual Analog Scale (VAS)

3

Description
The quality of urination
Timepoint
One, two, and three months after the intervention
Method of measurement
By taking history

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Tamsulosin tablets 0.4 mg (manufactured by Reihana Pharmaceutical Company) daily plus N-acetyl Cysteine tablets 600 mg (manufactured Ave Sina Pharmaceutical Company) every 12 hours for one month
Category
Treatment - Drugs

2

Description
Control group: Tamsulosin tablets 0.4 mg (manufactured by Reihana Pharmaceutical Company) daily plus placebo tablets (manufactured by laboratory of the School of Pharmacy, Hamadan University of Medical Sciences) every 12 hours for one month
Category
Placebo

Recruitment centers

1

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

1

Sponsor
Name of organization / entity
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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
Dr Maryam Mehrpooya
Position
Clinical Pharmacologist
Latest degree
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Other areas of specialty/work
Medical Pharmacy
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Person responsible for updating data

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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