

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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+98 81 1838 0090

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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

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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

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

Dr Maryam Mehrpooya

Position

Clinical Pharmacologist

Latest degree

Ph.D.

Other areas of specialty/work

Medical Pharmacy

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

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Other areas of specialty/work

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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

Position

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