

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Sep 2026

Evaluation of effect of acupuncture on treatment in patients with chronic nonbacterial

Protocol summary

Study aim

Comparison of the effectiveness of acupuncture treatment in patients with chronic prostatitis type 3

Design

A clinical trial with a control group, with parallel groups, double-blind, randomized. The method used to generate a random allocation sequence using the site: www.randomization.com will be used to generate a random sequence

Settings and conduct

Urology Clinic of Imam Reza Hospital in Mashhad

Participants/Inclusion and exclusion criteria

Age between 18 and 50 years; NIH Chronic Prostatitis Symptom Index (NIH-CPSI) total score ≥ 15 ; Pelvic pain and urinary symptoms lasting at least 3 to 6 months. Conditions of non-entry: history of prostatitis surgery. Taking certain medications that react to acupuncture.

Intervention groups

Individuals in the control group receive routine care (medical, educational, etc.) Tamsulosin capsules overnight, Naproxen 251 ml tablets every 02 hours, Toltorudine 2 mg ER per night). In the intervention group, in addition to the usual treatments, the patients also receive acupuncture treatments (10 sessions a day in between).

Main outcome variables

Perineal and anal pain, sometimes buttocks and groin tingling; tingling in the legs; pain in the testicles

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20101130005280N46**

Registration date: **2022-02-09, 1400/11/20**

Registration timing: **prospective**

Last update: **2022-02-09, 1400/11/20**

Update count: **0**

Registration date

2022-02-09, 1400/11/20

Registrant information

Name

Raheleh Nejati

Name of organization / entity

Mashhad University of Medical Scinces, Ibn-e- Sina Psychiatric Hospital

Country

Iran (Islamic Republic of)

Phone

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-03-03, 1400/12/12

Expected recruitment end date

2022-11-03, 1401/08/12

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of effect of acupuncture on treatment in patients with chronic nonbacterial

Public title

Evaluation of effect of acupuncture on chronic prostatitis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:	Age between 18 and 50 years NIH Chronic Prostatitis Symptom Index (NIH-CPSI) total score ≥ 15 Pelvic pain and urinary symptoms lasting at least 3 to 6 months.
	Exclusion criteria: Prostate surgery Taking certain medications that may react to acupuncture
Age	From 18 years old to 50 years old
Gender	Male
Phase	N/A
Groups that have been masked	- Participant - Outcome assessor
Sample size	Target sample size: 58
Randomization (investigator's opinion)	Randomized
Randomization description	This is how random numbers are prepared with the help of Randomaize.com. According to the number of research samples, a number of envelopes with wrappers Alumni (in order to avoid the clarity of the contents of the envelopes), are prepared and each of the random sequences created on a card is recorded and the cards inside the envelopes are better named. In order to maintain a random sequence, also on the outer surface of the envelopes. The issuance number is done in the same way. Finally, the lids of the letter envelopes are glued and placed inside a box, respectively. At the beginning of the registration of participants, based on the order of entry of eligible participants into the study, one of the envelopes of the letter is opened in order and the envelopes have the odd number of the control group and the envelopes have an even number.
Blinding (investigator's opinion)	Double blinded
Blinding description	People under study and outcome assessor are fully aware of the subject of research and the purpose and process of the study, and after filling out the consent and according to the entry conditions, will enter the study of the contents of the envelope and to which group they are assigned (control and intervention) (Because they do not predict the outcome) will be unaware.
Placebo	Not used
Assignment	Parallel
Other design features	
Secondary Ids	empty
Ethics committees	

<u>1</u>	
Ethics committee	
Name of ethics committee	Ethics committee of Mashhad University of Medical Science
Street address	Central Building of Mashhad University of Medical Sciences (Ghorshi), Daneshgah 16, Daneshgah Street
City	Mashhad
Province	Razavi Khorasan
Postal code	123456
Approval date	2022-01-23, 1400/11/03
Ethics committee reference number	IR.MUMS.MEDICAL.REC.1400.699
Health conditions studied	
<u>1</u>	
Description of health condition studied	Chronic prostatitis
ICD-10 code	N41.1
ICD-10 code description	Chronic prostatitis
Primary outcomes	
<u>1</u>	
Description	Perineal anal pain sometimes in the buttocks and groin
Timepoint	Beginning and end of the intervention
Method of measurement	Using the International Prostate Symptom Score and The NIH-Chronic Prostatitis Symptom Index (NIH-CPSI) questionnaires will be evaluated and the results before and after treatment will be compared.
<u>2</u>	
Description	Tingling and tingling in the legs
Timepoint	Beginning and end of the intervention
Method of measurement	Using the International Prostate Symptom Score and The NIH-Chronic Prostatitis Symptom Index (NIH-CPSI) questionnaires will be evaluated and the results before and after treatment will be compared.
<u>3</u>	
Description	Pain in the testicles
Timepoint	Pain in the testicles

Method of measurement

The use of international prostate symptom score questionnaires and The NIH-Chronic Prostatitis Symptom Index (NIH-CPSI) will be evaluated and the results before and after treatment will be compared.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: In the intervention group, in addition to the usual treatments (1. One tamsulosin capsule per night 2. Naproxen 251 mg tablets every 02 hours 3. Toltorudine 2 mg ER per night), the patients also receive acupuncture treatments (10 sessions a day in between).

Category

Diagnosis

2

Description

Control group: Individuals in the control group receive routine care (therapeutic, educational, etc.) (1. One tamsulosin capsule per night 2. Naproxen 251 mg tablets every 02 hours 3. Toltorudine 2 mg ER per night)

Category

Diagnosis

Recruitment centers

1

Recruitment center

Name of recruitment center

Acupuncture Center of Imam Reza Hospital

Full name of responsible person

Salman Soltani

Street address

Khorasan Razavi, Mashhad, University Street

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Majid Ghayour

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Central Building of Mashhad University of Medical Sciences (Ghorshi), Daneshgah 16, Daneshgah street

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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

Mashhad 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

Mashhad University of Medical Sciences

Full name of responsible person

Salman Soltani

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Urology

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Person responsible for scientific inquiries

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Person responsible for updating data

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Salman Soltani

Position

Assistant Professor

Latest degree

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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