Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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
+98 51 3711 2540

Email address
nejatir2@mums.ac.ir

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

1

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

1

Description of health condition studied
Chronic prostatitis

ICD-10 code
N41.1

ICD-10 code description
Chronic prostatitis

Primary outcomes

1

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.

2

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.

3

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
City
Mashhad
Province
Razavi Khorasan
Postal code
12345
Phone
+98 51 3879 5031
Email
SoltaniS@mums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Majid Ghayour
Street address
Central Building of Mashhad University of Medical Sciences (Ghorshi), Daneshgah 16, Daneshgah street
City
Mashhad
Province
Razavi Khorasan
Postal code
345 -91357
Phone
+98 51 3841 2081
Email
SoltaniS@mums.ac.ir
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
Street address
Khorasan Razavi, Mashhad, University Street
City
Mashhad
Province
Razavi Khorasan
Postal code
13944-91388
Phone
38795031 051
Email
SoltaniS@mums.ac.ir

Person responsible for scientific 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

Street address
Khorasan Razavi, Mashhad, University Street

City
Mashhad

Province
Razavi Khorasan

Postal code
99191-91778

Phone
38795031 051

Email
SoltaniS@mums.ac.ir

Person responsible for updating data

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

Street address
Khorasan Razavi, Mashhad, University Street

City
Mashhad

Province
Razavi Khorasan

Postal code
99191-91778

Phone
38795031 051

Email
SoltaniS@mums.ac.ir

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