

Clinical Trial Protocol

Iranian Registry of Clinical Trials

14 Jul 2026

Investigating the effects of acupressure on residual urine volume and dysuria in patients with benign prostatic hypertrophy

Protocol summary

Study aim

Determining the effect of real acupressure on chronic urinary retention in patients with benign prostatic hypertrophy

Design

This study is a clinical trial with a control group (acupressure on sham points) and an intervention (acupressure on main points), with parallel groups, one blind strain (patient), randomized. 10 patients will be tested as a pilot, and then the second phase study will be done using the sample size formula.

Settings and conduct

This study is a double-blind randomized clinical trial (patient and analyst) that will be conducted on all patients with benign prostatic hypertrophy referred to the urology clinic of Mashhad University of Medical Sciences in 2014. Before and after the intervention, information will be collected with a checklist containing demographic information and study variables.

Participants/Inclusion and exclusion criteria

inclusion criteria: Age over 45 years, diagnosis of Benign Prostatic Hyperplasia by a specialist doctor and confirmation of PVR above 100 ml with ultrasound and no coagulation disorders Criteria for non-entry: the person's unwillingness to participate in the study, having cognitive problems and not being able to learn and perform acupressure, having a history of acute kidney problems and kidney stones

Intervention groups

Intervention group: Patients with benign prostatic hypertrophy who complain of urinary retention will be treated with acupressure. Control group: will receive acupressure on negative sham-acupoints.

Main outcome variables

IPSS symptom score; the patient's urine output volume; dysuria; the remaining volume of urine after the end of the period; the average amount of urine excretion

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220608055105N1**

Registration date: **2022-11-03, 1401/08/12**

Registration timing: **retrospective**

Last update: **2022-11-03, 1401/08/12**

Update count: **0**

Registration date

2022-11-03, 1401/08/12

Registrant information

Name

Akram Kazem Karim Aljenahi

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 51 3859 1511

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-06-15, 1401/03/25

Expected recruitment end date

2022-07-06, 1401/04/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the effects of acupressure on residual urine volume and dysuria in patients with benign prostatic hypertrophy

Public title

The effects of acupressure on the volume of urine and the intensity of micturition pain caused by prostate enlargement

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Diagnosis of Benign prostate hypertrophy by a specialist
Confirmation of the residual volume of the disease after evacuation of more than 100 cc with ultrasound
No coagulation disorders

Exclusion criteria:

The patient has undergone prostate surgery
The patient is not conscious or it is not possible to put pressure on the pressure points by him

Age

From **45 years** old

Gender

Male

Phase

N/A

Groups that have been masked

- Participant
- Data analyser

Sample size

Target sample size: **20**

Randomization (investigator's opinion)

Randomized

Randomization description

Eligible samples are first available and then randomly allocated in two intervention and control groups. In order to randomize, we use an opaque envelope that contains numbers equal to the number of the sample (from 1 to 20), in such a way that every patient who comes, we remove one number from the envelope. If the number is odd, the patient will be assigned to The intervention group is entered, and if it is even, it is entered into the control group, this process continues until reaching the desired sample size.

Blinding (investigator's opinion)

Double blinded

Blinding description

The only person who knows about the patient's treatment will be an acupressure specialist, and the researcher and sonographer will not know about the patient's treatment group.

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 Sciences

Street address

Doctor Crossroads - Ibn Sina St. School of Nursing and Midwifery - Postal Code: 9137913199

City

Mashhad

Province

Razavi Khorasan

Postal code

9137913199

Approval date

2022-07-19, 1401/04/28

Ethics committee reference number

IR.MUMS.NURSE.REC.1401.061

Health conditions studied

1

Description of health condition studied

Benign prostatic hypertrophy

ICD-10 code

N40

ICD-10 code description

Enlarged prostate

Primary outcomes

1

Description

IPSS Symptom Score

Timepoint

6 sessions in 2 weeks

Method of measurement

Demographic information: Checklist containing patients' demographic information, IPSS symptom score (international prostate symptom score), volume of patient's voided urine: using a graduated container, starting time of voiding: by asking the patient, dysuria: by asking the patient, residual volume Urine before and 48 hours after the end of the course: with sonography

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Patients with benign prostatic hypertrophy who complain of urinary retention will be treated with acupressure on the affected points. The four

main points in acupressure (Pang guanshu, Guan yuan, Shen men, San yinjiao) will be placed with the fingers for one minute and three kilograms of pressure. The length of treatment is 6 sessions in 2 weeks. The first point of acupressure group is BL 28 or Pang guanshu. This point is located at a distance of 1.5 as lateral to the posterior midline of the body at the level of the second hole of the sacrum or sacrum. The second point of acupressure group is CV4 or Guan yuan. This point is located on the middle line of the front of the body at a distance of 3 cm below the navel. The third point of acupressure group is HT7 or Shen men. This point is located on the lowest inner crease of the wrist, immediately after the tendon of the flexor carpi ulnaris muscle and on the radial side of the tendon. The fourth point of acupressure group is SP6 or San yinjiao. This point is located at a distance of 3, because it is above the most prominent part of the inner ankle of the foot and immediately behind the tibia bone.

Category

Treatment - Other

2

Description

Control group: patients with benign prostatic hypertrophy who complain of urinary retention and will be treated with sham or ineffective acupressure (Cheng Jian, Fei shu, Shao hai, Gong sun). Four ineffective points (sham) in acupressure will be placed with a finger for one minute each and a pressure of three kilograms. The length of the treatment is 6 sessions in 2 weeks. The first point of the acupressure group is Sham CV 24 or Cheng Jian. This point is located in the midline of the front of the body under the lower lip and in the mentolabial groove. The second point of the acupressure group is Sham BL 13 or Fei shu. This point is located on the back of the body and in alignment with the lower edge of the third thoracic vertebra and at a distance of 1.5 cm lateral to the midline of the back of the body. The third point of the Sham acupressure group is HT3 or Shao hai. This point is located in the inner part of the elbow bend between the inner end of the elbow crease and the inner epicondyle of the humerus. The fourth point of the Sham acupressure group is SP4 or Gong sun. This point is on the surface The inside of the foot is located on the border of the white and red skin of the sole and exactly in the middle of the foot arch.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Urology Center of Imam Reza Hospital

Full name of responsible person

Hamid Chamanzari

Street address

University St., Doctora Intersection, Ibn Sina St., School of Nursing and Midwifery

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

No

Title of funding source

Research assistant of 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

Hamid Chamanzari

Position
Graduate student

Latest degree
Bachelor

Other areas of specialty/work
Nursery

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Master Student

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Urology

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Person responsible for scientific inquiries

Contact

Name of organization / entity
Mashhad University of Medical Sciences

Full name of responsible person
Hamid Chamanzari

Position
Graduate student

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Bachelor

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Nursery

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Person responsible for updating data

Contact

Name of organization / entity
Mashhad University of Medical Sciences

Full name of responsible person
Akram Kazem Karim Aljenahi

Position

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

Research units participating in this study Data include demographic characteristics, intervening variables, main variables (independent and dependent)

When the data will become available and for how long

From the beginning of July 2022 to December 2022

To whom data/document is available

Researcher, research assistant and statistics consultant

Under which criteria data/document could be used

The data is organized as an article and published in reputable journals

From where data/document is obtainable

Mr. Hamid Chamanzari/ Faculty of Nursing and Midwifery
Mashhad/ ChamanzariH@mums.ac.ir/ 05138591511

What processes are involved for a request to access data/document

By obtaining permission from Mashhad University of Medical Sciences and then sending the application email along with the permission to the study researcher's email

Comments