

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

Evaluation of oral administration of Peganum in nocturia in patients with benign prostatic hyperplasia

Protocol summary

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Summary

To determine oral administration of Peganum in nocturia in patients with benign prostatic hyperplasia, single-center, phase 3 trial, Single-blind 2) Participant: Inclusion criteria: Inclusion criteria: patients with benign prostatic enlargement. Exclusion criteria: patients undergoing surgery; a significant anomaly functional or anatomical urinary tract; thyroid dysfunction; prostate cancer; patients with mental disorders 3) Population: 70 patients divide in case and control 4) Interventions : intervention group will be used of harmala seeds 1 gr orally twice daily and the control group did not receive any treatment 5) Comparison: one months 6) Outcome: reduction of nocturia

Recruitment status

Recruitment complete

Funding source

Shahrekord University of Medical Sciences

Expected recruitment start date

2014-09-23, 1393/07/01

Expected recruitment end date

2015-03-21, 1394/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014091419151N1**

Registration date: **2014-09-19, 1393/06/28**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2014-09-19, 1393/06/28

Registrant information

Name

Majid Shirani

Name of organization / entity

Shahrekord University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 38 1333 0065

Email address

Scientific title

Evaluation of oral administration of Peganum in nocturia in patients with benign prostatic hyperplasia

Public title

Evaluation of oral administration of Peganum in nocturia in patients with benign prostatic hyperplasia

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: patients with benign prostatic enlargement. Exclusion criteria: patients undergoing surgery; a significant anomaly functional or anatomical urinary tract; thyroid dysfunction; prostate cancer; patients with mental disorders

Age

No age limit

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: 70

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Used

Assignment

Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Shahrekord University of Medical Sciences

Street address

Shahrekord,Rahmatieh, Shahrekord University of
Medical Sciences

City

Shahrekord

Postal code

Approval date

2013-09-08, 1392/06/17

Ethics committee reference number

4-5-92

Health conditions studied

1

Description of health condition studied

Hyperplasia of prostate

ICD-10 code

N40

ICD-10 code description

Hyperplasia of prostate

Primary outcomes

1

Description

decrease of nocturia

Timepoint

1 months latter

Method of measurement

examination

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group will be used of harmala seeds1 gr orally twice daily.

Category

Treatment - Drugs

2

Description

the control group did not receive any treatment.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

shahrekord urology clinic

Full name of responsible person

Shirani Majid

Street address

Shahrekord, Shahrekord University Of Medical
Sciences

City

Shahrekord

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research of Shahrekord University
of Medical Scie

Full name of responsible person

Vice chancellor for research of Shahrekord University
of Medical Scie

Street address

Shahrekord, Shahrekord University of Medical
Sciences

City

Shahrekord

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice chancellor for research of Shahrekord University of
Medical Scie

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

empty

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

Shahrekord University of Medical Sciences

Full name of responsible person

Shirani Majid

Position

Urological Surgeons, Assistant Professor

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty