

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

03 Jun 2026

### The Comparison of Equisetum arvense , Urtica dioecia and Sedlitzia rosmarinus effects on clinical symptoms of Benign Prostatic Hyperplasia

#### Protocol summary

##### Summary

This randomized double-blind clinical trial was conducted to compare the effects of three herbal drugs including Equisetum arvense , Urtica dioecia and Sedlitzia rosmarinus on clinical symptoms of Benign Prostatic Hyperplasia . The number of 620 Subjects selected from new BPH cases referred to Shohadaye Ashayer urology clinic and did not have history of prostate cancer ,CRF, DM and CHF. After convenience sampling, by randomized block design subjects were allocated to four groups including Equisetum arvense plus prazosin (n=186), Urtica dioecia plus prazosin (n=186) and Sedlitzia rosmarinus plus prazosin (n=186) and only prazosin as control group(n=62). The subjects of each group were allocated again to three groups of 3gr/day, 5 gr/day and 7 gr/day. The subjects were advised to take the prescribed herbal drug one time daily for two months. Before and after 2 months of intervention by AUA questionnaire storage and voiding clinical symptoms and serum PSA of patients were measured. The scores of clinical symptoms and serum PSA of each group were compared before and after the intervention. The mean recovery scores of clinical symptoms and serum PSA of subjects in all groups were compared after the intervention.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201208279302N2**  
Registration date: **2012-09-22, 1391/07/01**  
Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2012-09-22, 1391/07/01

#### Registrant information

##### Name

Reza Hosseinabadi

##### Name of organization / entity

Lorestan University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 66 1620 0140

##### Email address

reza.hosseinabadi@lums.ac.ir

#### Recruitment status

##### Recruitment complete

#### Funding source

Lorestan University of Medical sciences

#### Expected recruitment start date

2012-07-22, 1391/05/01

#### Expected recruitment end date

2013-01-09, 1391/10/20

#### Actual recruitment start date

empty

#### Actual recruitment end date

empty

#### Trial completion date

empty

#### Scientific title

The Comparison of Equisetum arvense , Urtica dioecia and Sedlitzia rosmarinus effects on clinical symptoms of Benign Prostatic Hyperplasia

#### Public title

Effect of herbal Drugs on Benign prostatic hyperplasia symptoms

#### Purpose

Treatment

#### Inclusion/Exclusion criteria

Inclusion Criteria: Age of 49 and above; New BPH diagnosed cases; To have storage or voiding symptoms; AUA score of 7 and above; Urine Bacterial count less

than 100000/ml; Serum ceartinine less than 1.5 mg/dl; PSA less than 4 n/ml Exclusion criteria: To have history of prostate cancer; To have prostatitis; Neurogenic bladder cases; To have Diabetes mellitus; To have Nephropathy; To have CHF; To have Renal failure; To have more than two antihypertensive drugs; To have non prescriptive herbal drugs;

#### Age

From **49 years** old to **85 years** old

#### Gender

Male

#### Phase

N/A

#### Groups that have been masked

*No information*

#### Sample size

Target sample size: **620**

#### Randomization (investigator's opinion)

Randomized

#### Randomization description

#### Blinding (investigator's opinion)

Double blinded

#### Blinding description

#### Placebo

Used

#### Assignment

Parallel

#### Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethice committee of Lorestan University of Medical Sciences

##### Street address

Kamalvand, Khorramabad, Iran

##### City

Khorramabad

##### Postal code

#### Approval date

2012-07-14, 1391/04/24

#### Ethics committee reference number

200/70670

## Health conditions studied

### 1

#### Description of health condition studied

Benign Hypertrophy of prostate

#### ICD-10 code

N40

#### ICD-10 code description

Hypertrophy (benign) of prostate

## Primary outcomes

### 1

#### Description

storage or voiding clinical symptoms

#### Timepoint

Before and 2 months after the intervention

#### Method of measurement

AUA Questionnaire

## Secondary outcomes

### 1

#### Description

Serum PSA

#### Timepoint

Before and 2 months after the intervention

#### Method of measurement

Blood laboratory test

## Intervention groups

### 1

#### Description

The Seidlitzia rosmarinus group3 (n=62): Seidlitzia rosmarinus 3 gr/day plus perazisin at 1 mg daily for two months

#### Category

Treatment - Drugs

### 2

#### Description

The Urtica dioecia group3 (n=62): Urtica dioecia 3 gr/day plus perazisin at 1 mg daily for two months

#### Category

Treatment - Drugs

### 3

#### Description

The Seidlitzia rosmarinus group5 (n=62): Seidlitzia rosmarinus 5 gr/day plus perazisin at 1 mg daily for two months

#### Category

Treatment - Drugs

### 4

#### Description

The Equisetum arvense group7 (n=62): Equisetum arvense 7 gr/day plus perazisin at 1 mg daily for two months

#### Category

Treatment - Drugs

### 5

#### Description

The Urtica dioecia group5 (n=62): Urtica dioecia 5 gr/day plus perazisin at 1 mg daily for two months

**Category**

Treatment - Drugs

**6**

**Description**

The Urtica dioecia group7 (n=62): Urtica dioecia 7 gr/day plus perazisin at 1 mg daily for two months

**Category**

Treatment - Drugs

**7**

**Description**

The Equisetum arvense group3 (n=62): Equisetum arvense3 gr/day plus perazisin at 1 mg daily for two months

**Category**

Treatment - Drugs

**8**

**Description**

The Equisetum arvense group5 (n=62): Equisetum arvense 5 gr/day plus perazisin at 1 mg daily for two months

**Category**

Treatment - Drugs

**9**

**Description**

The Seidlitzia rosmarinus group7(n=62): Seidlitzia rosmarinus 7 gr/day plus perazisin at 1 mg daily for two months

**Category**

Treatment - Drugs

**10**

**Description**

The control group(n= 62): only perazisin at 1 mg daily for two months

**Category**

Treatment - Drugs

**Recruitment centers**

**1**

**Recruitment center**

**Name of recruitment center**

Shohadaye Ashayer Urology Clinic

**Full name of responsible person**

Mohammad Heydari

**Street address**

Enghelab Street,Shohadaye Ashayer Hospitals

**City**

Khorramabad

**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

Razi Herbal Medicine Research Center of Lorestan  
University of Medical Sciences

**Full name of responsible person**

Bahram Rasoolian

**Street address**

Kmalvand, Khorramabad,Iran

**City**

Khorramabad

**Grant name**

**Grant code / Reference number**

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

Yes

**Title of funding source**

Razi Herbal Medicine Research Center of Lorestan  
University of Medical Sciences

**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**

Lorestan University of Medical Sciences, School of  
Nursing & Midwifery

**Full name of responsible person**

Reza Hosseinabadi

**Position**

MSc in Nursing

**Other areas of specialty/work**

**Street address**

Kamalvand, Khorramabad, Iran

**City**

Khorramabad

**Postal code**

6819846531

**Phone**

+98 66 1620 0140

**Fax**

**Email**

reza\_hosseinabadi@yahoo.com

**Web page address**

**Person responsible for scientific inquiries**

**Contact**

**Name of organization / entity**

Lorestan University of Medical Sciences, School of  
Medicine

**Full name of responsible person**

Mohammad Heidari

**Position**

Professor of Urology

**Other areas of specialty/work****Street address**

Enghelab Street, Shohadaye Ashayer Hospitals

**City**

Khorramabad

**Postal code****Phone**

+98 66 1323 6401

**Fax****Email**

Mheydari2010@yahoo.com

**Web page address****Person responsible for updating data****Contact****Name of organization / entity**

Lorestan University of Medical Sciences, School of  
Nursing & Midwifry

**Full name of responsible person**

Reza Hosseinabadi

**Position**

MSc in nursing

**Other areas of specialty/work****Street address**

Kmalvand, Khorramabad, Iran

**City**

Khorramabad

**Postal code**

6819848464

**Phone**

+98 66 1620 0140

**Fax****Email**

reza\_hosseinabadi@yahoo.com

**Web page address****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*