

Clinical Trial Protocol

Iranian Registry of Clinical Trials

12 Jul 2026

The effect of the ethanol injection in prostate tissue versus no injection for treatment of benign prostatic hyperplasia: a before after clinical trial

Protocol summary

Summary

Objectives: To assess the effect of the ethanol injection in prostate tissue versus no injection for treatment of benign prostatic hyperplasia. **Design:** A before after clinical trial. **Setting and conduct:** All eligible patients with benign prostatic hyperplasia who will refer to Shahid Beheshti Hospital during the study period will be enrolled in to the trial. **Inclusion criteria:** (a) patients with benign prostatic hyperplasia; (b) age of 40 years or older; (c) contraindication for prostatic surgery; (d) Unable to tolerate adverse effect of prostatic drug treatment; (e) prostatic surgery refusal. **Exclusion criteria:** (a) history of prostatic surgery; (b) having prostatic cancer. **Intervention:** injection of 10 to 20 ml alcohol 98% into prostatic tissue in 4 to 10 location. **Control:** comparison with situation before intervention. **Primary outcome:** (a) evaluation of urinary problem using International Prostatic Symptoms Scale-IPSS before surgery and 3 and 6 months later; (b) evaluation of maximum urine flow using Peak Flow Rate before surgery and 3 and 6 months later; (c) measuring the prostatic volume using ultrasonography before surgery and 3 and 6 months later; (d) measuring the remained urine volume using ultrasonography before surgery and 3 and 6 months later; (e) measuring the prostatic specific antigen (PSA) through blood sampling before surgery and 3 and 6 months later. **Secondary outcome:** measuring the injection induced pain using visual analog scale (VAS) immediately after injection.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201407049014N39**

Registration date: **2014-07-04, 1393/04/13**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2014-07-04, 1393/04/13

Registrant information

Name

Jalal Poorolajal

Name of organization / entity

Department of Epidemiology & Biostatistics Hamadan
University of Medical Sciences

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Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Vice-chancellor for Research the Technology, Hamadan
University of Medical Sciences

Expected recruitment start date

2014-07-23, 1393/05/01

Expected recruitment end date

2015-07-23, 1394/05/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of the ethanol injection in prostate tissue versus no injection for treatment of benign prostatic hyperplasia: a before after clinical trial

Public title

The effect of the ethanol injection in prostate tissue

versus no injection for treatment of benign prostatic hyperplasia

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: (a) patients with benign prostatic hyperplasia; (b) age of 40 years or older; (c) contraindication for prostatic surgery; (d) Unable to tolerate adverse effect of prostatic drug treatment; (e) prostatic surgery refusal. Exclusion criteria: (a) history of prostatic surgery; (b) having prostatic cancer.

Age

From **40 years** old to **80 years** old

Gender

Male

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **31**

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Single

Other design features

Randomization: This trial will be run as a before-after design; hence no randomization will be done. Blinding: This is an aggressive intervention; hence blinding is impossible.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethic Committee of Hamadan University of Medical Sciences

Street address

Vice-chancellor of Research the Technology,
Hamadan University of Medical Sciences, Shahid
Fahmideh Ave

City

Hamadan

Postal code

6517838695

Approval date

2014-06-25, 1393/04/04

Ethics committee reference number

D/P/16/35/9/1541

Health conditions studied

1

Description of health condition studied

Benign Prostate Hyperplasia

ICD-10 code

N40

ICD-10 code description

Hyperplasia of prostate

Primary outcomes

1

Description

evaluation of urinary problem

Timepoint

before surgery and 3 and 6 months later

Method of measurement

using International Prostatic Symptoms Scale-IPSS

2

Description

evaluation of maximum urine flow

Timepoint

before surgery and 3 and 6 months later

Method of measurement

using Peak Flow Rate

3

Description

measuring the prostatic volume

Timepoint

before surgery and 3 and 6 months later

Method of measurement

using ultrasonography

4

Description

measuring the remained urine volume

Timepoint

before surgery and 3 and 6 months later

Method of measurement

using ultrasonography

5

Description

measuring the prostatic specific antigen (PSA)

Timepoint

before surgery and 3 and 6 months later

Method of measurement

through blood sampling

Secondary outcomes

1

Description

measuring the injection induced pain

Timepoint

immediately after injection

Method of measurement

using visual analog scale (VAS)

Intervention groups

1

Description

injection of 10 to 20 ml alcohol 98% into prostatic tissue in 4 to 10 location

Category

Treatment - Drugs

2

Description

comparison with situation before intervention

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Beheshti Hospital

Full name of responsible person

Dr Mohammad Reza Mojallali

Street address

Shahid Beheshti Hospital, Eram Bul.

City

Hamadan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice-chancellor for Research the Technology,
Hamadan University of Medical Sciences

Full name of responsible person

Dr Saeid Bashirian

Street address

Hamadan University of Medical Sciences, Shahid
Fahmideh Ave

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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

Vice-chancellor for Research the Technology, Hamadan

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

Shahid Beheshti Hospital

Full name of responsible person

Dr Mohammad Reza Mojallali

Position

Resident of Urology

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

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Full name of responsible person

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Web page address

Person responsible for updating data

Contact

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