

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

16 Sep 2026

### Evaluation of efficacy and complications of prostatic arterial embolization in the treatment of BPH

#### Protocol summary

##### Summary

The aim of this study is to evaluate of efficacy and complications of prostatic arterial embolization in the treatment of BPH Benign prostate hyperplasia. Inclusion criteria: Men aged over 60 years having benign prostatic hyperplasia, no respond to medical treatment after 6 months, having sexual dysfunction, having maximum flow rate (Qmax) less than 12 mm/s in urine flowmeter. Exclusion criteria: malignancy and tortuosity atherosclerotic Iliac artery, having any indication for renal surgery such as hematuria, bladder diverticula, stones, etc. Symptomatic patients who have been treated by other clinical methods at least 6 months but their treatment was not satisfied are elected to this method. The estimated sample size will be 12 people. Then pelvic angiography is done to evaluate prostate artery. Total time of the procedure is measured from femoral artery puncture until bring out the catheter. Clinical success is considered to be a decrease in International Prostate Symptom Score IPSS<20 and improve Qmax>7ml/s.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2015100318457N2**

Registration date: **2016-06-16, 1395/03/27**

Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2016-06-16, 1395/03/27

##### Registrant information

##### Name

Hossein Ghanaati

##### Name of organization / entity

Advanced Diagnostic and Interventional Radiology  
Research Center (ADIR), Tehran University of Medica

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 6658 1516

##### Email address

ghenaati@tums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Tehran University of Medical Sciences

##### Expected recruitment start date

2015-11-22, 1394/09/01

##### Expected recruitment end date

2017-05-22, 1396/03/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Evaluation of efficacy and complications of prostatic  
arterial embolization in the treatment of BPH

##### Public title

treatment of enlargement of prostatic by Closing the  
feeder vessels

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

Inclusion criteria: Men aged over 60 years having benign  
prostatic hyperplasia; no respond to medical treatment  
after 6 months, having sexual dysfunction, having  
maximum flow rate (Qmax) less than 12 mm/s in urine;  
;acute urinary retention . Exclusion criteria: malignancy;  
tortuosity and atherosclerotic iliac artery; having any

indication for renal surgery such as hematuria, bladder diverticula, stones

### Age

From **55 years** old to **35 years** old

### Gender

Male

### Phase

N/A

### Groups that have been masked

*No information*

### Sample size

Target sample size: **12**

### Randomization (investigator's opinion)

N/A

### Randomization description

### Blinding (investigator's opinion)

Not blinded

### Blinding description

### Placebo

Not used

### Assignment

Single

### Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Tehran University of Medical Sciences

##### Street address

Ghods street- Keshavarz Bulivar

##### City

Tehran

##### Postal code

#### Approval date

2015-05-21, 1394/02/31

#### Ethics committee reference number

IR.TUMS.REC.1394-211

## Health conditions studied

### 1

#### Description of health condition studied

Benign Prostatic Hyperplasia

#### ICD-10 code

N40

#### ICD-10 code description

Hyperplasia of Prostate

## Primary outcomes

### 1

#### Description

Q max

#### Timepoint

befor intrvention and 1,3,6 months after intervention

#### Method of measurement

uroflowmetry

### 2

#### Description

IPSS

#### Timepoint

befor intrvention and 1,3,6 months after intervention

#### Method of measurement

Questionnaire

### 3

#### Description

Prostat size

#### Timepoint

befor intrvention and 1,3,6 months after intervention

#### Method of measurement

Sonography

### 4

#### Description

PSA level

#### Timepoint

befor intrvention and 1,3,6 months after intervention

#### Method of measurement

lab

## Secondary outcomes

### 1

#### Description

contrast media side effectS

#### Timepoint

during procedure and after 24 hours

#### Method of measurement

question from patient and clinical examination

### 2

#### Description

sexual dysfunction

#### Timepoint

6 months after surgery

#### Method of measurement

question from patients

### 3

#### Description

dont response to embolization and need to surgery

#### Timepoint

after 6 months

#### Method of measurement

question from patients

## Intervention groups

1

### Description

Prostatic Artery Embolization using polyvinyl guided by Angiographic catheter into the artery of the Prostate

### Category

Treatment - Other

## Recruitment centers

1

### Recruitment center

#### Name of recruitment center

Medical Imaging Center

#### Full name of responsible person

Nafiseh Ghavami

#### Street address

Emem Khomeini Hospital- Medical Imaging Center

#### City

Tehran

## Sponsors / Funding sources

1

### Sponsor

#### Name of organization / entity

Tehran University of Medical Sciences

#### Full name of responsible person

Mrs Akbari

#### Street address

Ghods Streer, Keshavarz Bulivar

#### City

Tehran

### Grant name

### Grant code / Reference number

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

Yes

### Title of funding source

Tehran 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

Advanced And Interventional Radiology Research

Center

#### Full name of responsible person

Amir Hossein Jalali

#### Position

General Practitioner

#### Other areas of specialty/work

#### Street address

Emem Khomeini Hospital-Medical Imaging Center

#### City

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#### Postal code

#### Phone

+98 21 6658 1579

#### Fax

#### Email

Amirjalali51@yahoo.com

#### Web page address

## Person responsible for scientific inquiries

### Contact

#### Name of organization / entity

Medical Imaging Center

#### Full name of responsible person

Dr Hossein Ghanaati

#### Position

Radiology Professor

#### Other areas of specialty/work

#### Street address

Emam Khomeini Hospital

#### City

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+66 581516

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ghanaati@yahoo.com

#### Web page address

## Person responsible for updating data

### Contact

#### Name of organization / entity

Advanced And Interventional Radiology Research Center

#### Full name of responsible person

Nafiseh Ghavami

#### Position

Ms/Expert Research

#### Other areas of specialty/work

#### Street address

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#### Postal code

#### Phone

+98 21 6658 1579

#### Fax

#### Email

ghavami\_7@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*