

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 Medical Sciences

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

Tehran

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

Tehran

Postal code

Phone

+66 581516

Fax

Email

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

City

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