

Clinical Trial Protocol

Iranian Registry of Clinical Trials

15 Sep 2026

The Effect of Transurethral Resection of the Prostate monopolar VS bipolar on Erectile Function in Patients with Benign Prostatic Hyperplasia

Protocol summary

Study aim

Evaluation of the incidence of erectile dysfunction after TURP surgery by monopolar and bipolar methods

Design

Clinical trial with two parallel groups of monopolar and bipolar and double-blind and randomized with Excel software on 229 patients

Settings and conduct

The study was performed in Al-Zahra Hospital in Isfahan. Patients who were candidates for prostate surgery underwent turp under either monopolar or bipolar methods. Nesbit method was used for resection. Patients and patient data collector were blind to the patient group

Participants/Inclusion and exclusion criteria

Admission requirements: People over the age of 50 who need prostate resection surgery who are sexually active and have regular sex with a sexual partner Conditions of non-entry: having a urethral catheter for more than one month; high psa (prostate specific antigen)

Intervention groups

Monopolar group: Prostate resection in this group is performed using a 26 french monopolar resectoscope. Bipolar Group: Prostate resection in this group is performed using a 26 french bipolar resectoscope

Main outcome variables

Patients 'IIEF score and patients' erectile function after surgery

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210212050335N1**

Registration date: **2021-04-07, 1400/01/18**

Registration timing: **prospective**

Last update: **2021-04-07, 1400/01/18**

Update count: **0**

Registration date

2021-04-07, 1400/01/18

Registrant information

Name

masoud sadat

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 35 3823 0130

Email address

sm.sadat155@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-05-22, 1400/03/01

Expected recruitment end date

2022-01-20, 1400/10/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effect of Transurethral Resection of the Prostate monopolar VS bipolar on Erectile Function in Patients with Benign Prostatic Hyperplasia

Public title

The Effect of Transurethral Resection of the Prostate monopolar VS bipolar on Erectile Function in Patients with Benign Prostatic Hyperplasia

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:
married sexual active continuous sexual activity with one partner have indication for benign prostatic hyperplasia surgery

Exclusion criteria:

Age

From **50 years** old

Gender

Male

Phase

N/A

Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **219**

Randomization (investigator's opinion)

Randomized

Randomization description

The study population was randomly divided into two groups. Randomization was performed by simple method. It was an individual randomization unit. A list of random numbers made with computer statistical software was used. Due to the fact that patients underwent general anesthesia during the operation, they were unaware of the device used for prostate resection. It was not possible to blind the surgeon. However, the collectors of data on sexual function before and after the operation and the analyzers of the data were blind to the intervention.

Blinding (investigator's opinion)

Double blinded

Blinding description

In this study, the patient was unaware of prostate resection (monopolar or bipolar) The person collecting the information is also unaware of the surgical procedure performed on each patient.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Isfahan University of Medical Sciences

Street address

Al-Zahra Hospital, Soffeh Street

City

Isfahan

Province

Isfahan

Postal code

8916885675

Approval date

2020-05-04, 1399/02/15

Ethics committee reference number

IR.MUI.MED.REC.1399.121

Health conditions studied

1

Description of health condition studied

Erectile dysfunction, benign prostate hyperplasia

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Patients' erectile function score based on IIEF15 questionnaire

Timepoint

Before surgery, 6 weeks and 6 months after surgery

Method of measurement

Questionnaire IIEF15

Secondary outcomes

empty

Intervention groups

1

Description

All operations were performed by a single surgeon. Monopolar TURP was performed in the first group and Bipolar TURP was performed in the second group. In both groups, the procedure was performed by routine Nesbit method. The current setting used for resection in the monopolar system was cut / coag 110/80 and for resection in the bipolar system was cut / coag 120/80. In both procedures, a 26-french continuous-flow resectoscope was used.

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Al-Zahra Hospital of Isfahan

Full name of responsible person

MohammadHatef Khorrami

Street address

Al-Zahra Hospital, Soffeh Street

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Latest degree

Medical doctor

Other areas of specialty/work

Urology

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Sponsors / Funding sources

1

Sponsor**Name of organization / entity**

Esfahan University of Medical Sciences

Full name of responsible person

Maryam Toghyani

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Al-Zahra Hospital, Soffeh Street

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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

Esfahan University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

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

Academic

Person responsible for general inquiries

Contact**Name of organization / entity**

Esfahan University of Medical Sciences

Full name of responsible person

Sayed Masoud Sadat

Position

Specialist Assistant in Urology

Person responsible for scientific inquiries

Contact**Name of organization / entity**

Esfahan University of Medical Sciences

Full name of responsible person

Sayed Masoud Sadat

Position

Specialist Assistant in Urology

Latest degree

Medical doctor

Other areas of specialty/work

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Person responsible for updating data

Contact**Name of organization / entity**

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Full name of responsible person

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Position

Specialist Assistant in Urology

Latest degree

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Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

There is no more information

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available