

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

18 Sep 2026

### Sexual sparing radical cystectomy: nerve sparing versus prostate capsule sparing

#### Protocol summary

##### Study aim

To evaluate and compare prostate capsule sparing and nerve sparing radical cystectomy impact on the oncological and functional outcomes of patients with muscle invasive bladder tumors

##### Design

All the patients were sexually active preoperatively (IIEF-5=22-25). The postoperative sexual function and continence were assessed by the International Index of Erectile Function (IIEF-15) and International Consultation on Incontinence Questionnaire (ICIQ) respectively and compared in groups A and B.

##### Settings and conduct

Between March, 2016 and September 2019, 60 men with muscle invasive bladder tumor who were candidate for sexual preserving radical cystectomy and orthotopic urinary diversion were included in this study. The cases were randomized in two groups. Nerves sparing radical cystectomy and prostate capsule sparing radical cystectomy.

##### Participants/Inclusion and exclusion criteria

men with muscle invasive bladder tumor who were candidate for sexual preserving radical cystectomy and orthotopic urinary diversion

##### Intervention groups

Nerves sparing radical cystectomy and prostate capsule sparing radical cystectomy

##### Main outcome variables

IIEF-15 (international index of erectile function)

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20211208053328N1**

Registration date: **2022-01-02, 1400/10/12**

Registration timing: **retrospective**

Last update: **2022-01-02, 1400/10/12**

Update count: **0**

##### Registration date

2022-01-02, 1400/10/12

##### Registrant information

###### Name

Hossein Bahrami Samani

###### Name of organization / entity

###### Country

Iran (Islamic Republic of)

###### Phone

+98 31 3620 2020

###### Email address

bahrami.hossein1993@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2016-03-01, 1394/12/11

##### Expected recruitment end date

2019-09-30, 1398/07/08

##### Actual recruitment start date

2016-03-01, 1394/12/11

##### Actual recruitment end date

2019-09-30, 1398/07/08

##### Trial completion date

2019-09-30, 1398/07/08

##### Scientific title

Sexual sparing radical cystectomy: nerve sparing versus prostate capsule sparing

##### Public title

Sexual sparing radical cystectomy: nerve sparing versus prostate capsule sparing

##### Purpose

Prevention

##### Inclusion/Exclusion criteria

**Inclusion criteria:**

candidate for sexual sparing radical cystectomy and orthotopic urinary diversion organ-confined diseases absence of any kind of tumor at the level of the prostate, prostatic urethra or bladder neck patients who are sexually active and enthusiastic to save their sexual functions

**Exclusion criteria:**

**Age**

From **49 years** old to **75 years** old

**Gender**

Male

**Phase**

N/A

**Groups that have been masked**

No information

**Sample size**

Target sample size: **120**

Actual sample size reached: **120**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Randomization will be performed by Randomizer software (Fahmy Corporation version 2016.6.0.56). It should be noted that patients are not aware of the procedure performed and the allocation is done secretly.

**Blinding (investigator's opinion)**

Not blinded

**Blinding description**

**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**

Vice Chancellor for Research and Technology, Hezar Jerib St. Isfahan University of Medical Sciences and Health Services, Building No. 4

**City**

Isfahan

**Province**

Isfahan

**Postal code**

8174673461

**Approval date**

2020-06-23, 1399/04/03

**Ethics committee reference number**

IR.MUI.MED.REC.1399.248

**Health conditions studied**

**1**

**Description of health condition studied**

Sexual sparing radical cystectomy

**ICD-10 code**

N52.32

**ICD-10 code description**

Erectile dysfunction following radical cystectomy

**Primary outcomes**

**1**

**Description**

international index of erectile function (IIEF)

**Timepoint**

6 months, 1 year and 2 years after surgery

**Method of measurement**

ICIQ (international consultation on incontinence questionnaire) and IIEF-15 (international index of erectile function)

**Secondary outcomes**

empty

**Intervention groups**

**1**

**Description**

Intervention group: Removal of bladder, prostate, seminal vesicle, vas deferens and pelvic lymph node lymphadenectomy will be performed with special attention to neurovascular bundles on the lateral edge of the prostate. All the principles of saving neurovascular bundles will be considered.

**Category**

Treatment - Surgery

**2**

**Description**

Intervention group: The prostate adenoma will be enucleated like Millin procedure and the capsule will be preserved for the neo-bladder anastomosis.

**Category**

Treatment - Surgery

**Recruitment centers**

**1**

**Recruitment center**

**Name of recruitment center**

Alzahra Hospital

**Full name of responsible person**

Hossein Bahrami Samani

**Street address**

Alzahra Hospital, Sofeh Blvd.

**City**  
Isfahan  
**Province**  
Isfahan  
**Postal code**  
8174675731  
**Phone**  
+98 31 3620 2020  
**Email**  
alzahra@mui.ac.ir

## 2

### **Recruitment center**

**Name of recruitment center**  
Khorshid Hospital  
**Full name of responsible person**  
Hossein Bahrami Samani  
**Street address**  
Khorshid Hospital, Ostandari st.  
**City**  
Isfahan  
**Province**  
Isfahan  
**Postal code**  
8145831451  
**Phone**  
+98 31 3222 2127  
**Email**  
nour@mui.ac.ir

## **Sponsors / Funding sources**

### 1

#### **Sponsor**

**Name of organization / entity**  
Esfahan University of Medical Sciences  
**Full name of responsible person**  
Mansour Siavash  
**Street address**  
Vice Chancellor for Research and Technology, Hezar  
Jerib St.sfahan University of Medical Sciences and  
Health Services, Building No. 4,  
**City**  
Isfahan  
**Province**  
Isfahan  
**Postal code**  
8174673461  
**Phone**  
+98 31 3668 8138  
**Email**  
research@mui.ac.ir

#### **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**  
Hossein Bahrami Samani  
**Position**  
Resident  
**Latest degree**  
Medical doctor  
**Other areas of specialty/work**  
Urology  
**Street address**  
Alzahra Hospital, Sofeh Blvd.  
**City**  
Isfahan  
**Province**  
Isfahan  
**Postal code**  
8174675731  
**Phone**  
+98 31 3620 2020  
**Email**  
bahrami.hossein1993@gmail.com

## **Person responsible for scientific inquiries**

### **Contact**

**Name of organization / entity**  
Esfahan University of Medical Sciences  
**Full name of responsible person**  
Hossein Bahrami Samani  
**Position**  
Resident  
**Latest degree**  
Medical doctor  
**Other areas of specialty/work**  
Urology  
**Street address**  
Alzahra Hospital, Sofeh Blvd.  
**City**  
Isfahan  
**Province**  
Isfahan  
**Postal code**  
8174675731  
**Phone**  
+98 31 3620 2020  
**Email**

## Person responsible for updating data

### Contact

**Name of organization / entity**

Esfahan University of Medical Sciences

**Full name of responsible person**

Hossein Bahrami Samani

**Position**

Resident

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Urology

**Street address**

Alzahra Hospital, Sofeh Blvd.

**City**

Isfahan

**Province**

Isfahan

**Postal code**

8174675731

**Phone**

+98 31 3620 2020

**Email**

bahrami.hossein1993@gmail.com

## 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**

Information is kept confidential

**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**

Undecided - It is not yet known if there will be a plan to make this available

**Clinical Study Report**

Yes - There is a plan to make this available

**Analytic Code**

Undecided - It is not yet known if there will be a plan to make this available

**Data Dictionary**

Not applicable

**Title and more details about the data/document**

Information about the main outcome can be shared

**When the data will become available and for how long**

After publishing the results

**To whom data/document is available**

Researchers working in academic and scientific institutions

**Under which criteria data/document could be used**

Using data to complete studies

**From where data/document is obtainable**

Dr. Hossein Bahrami Samani, Isfahan University of Medical Sciences

**What processes are involved for a request to access data/document**

By examining the researcher's request and providing sufficient documentation of his research and the reason for using the data can be provided

**Comments**