

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

16 Sep 2026

### LigaSure versus Stapling Device for Ligation of Bladder Pedicle on Erectile Function after Nerve Sparing Radical Cystectomy

#### Protocol summary

##### Study aim

Comparison of erectile function following nerve-sparing radical cystectomy using two method of ligating posterior bladder pedicle: Ligasure versus stapling device

##### Design

Randomized, blinded clinical trial with parallel groups

##### Settings and conduct

This study was performed in a university hospital called Al-Zahra, Isfahan, Iran. Before surgery all participants were asked to fill Erectile Function Questionnaire. The patients were randomized into two groups: in group one, posterior bladder pedicle was ligated using LigaSure, but in group two, posterior bladder pedicle was ligated by stapling device. Six months after the surgery, the patients were asked to refill the questionnaire.

##### Participants/Inclusion and exclusion criteria

Male under 70 year-old of age with muscle invasive bladder cancer candidate for radical cystectomy with orthotrophic urinary diversion without prior severe erectile dysfunction

##### Intervention groups

Group 1: ligation of posterior bladder pedicle by LigaSure  
Group 2: ligation of posterior bladder pedicle by stapling device

##### Main outcome variables

The status of erectile function

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20150420021869N2**

Registration date: **2019-05-21, 1398/02/31**

Registration timing: **retrospective**

Last update: **2019-05-21, 1398/02/31**

Update count: **0**

##### Registration date

2019-05-21, 1398/02/31

##### Registrant information

###### Name

Farshad Gholipour

###### Name of organization / entity

Tehran University of Medical Sciences

###### Country

Iran (Islamic Republic of)

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###### Email address

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##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2018-01-21, 1396/11/01

##### Expected recruitment end date

2019-01-21, 1397/11/01

##### Actual recruitment start date

2016-05-25, 1395/03/05

##### Actual recruitment end date

2017-05-22, 1396/03/01

##### Trial completion date

2018-05-22, 1397/03/01

##### Scientific title

LigaSure versus Stapling Device for Ligation of Bladder Pedicle on Erectile Function after Nerve Sparing Radical Cystectomy

##### Public title

LigaSure versus Stapling Device for Ligation of Bladder Pedicle on Erectile Function after Nerve Sparing Radical Cystectomy

##### Purpose

Treatment

## **Inclusion/Exclusion criteria**

### **Inclusion criteria:**

male patients younger than 70 years suffering muscle invasive bladder cancer candidate for radical cystectomy with orthotopic urinary diversion

### **Exclusion criteria:**

patients with severe erectile dysfunction

## **Age**

To **70 years** old

## **Gender**

Male

## **Phase**

N/A

## **Groups that have been masked**

- Participant
- Investigator
- Outcome assessor
- Data analyser

## **Sample size**

Target sample size: **64**

Actual sample size reached: **63**

More than 1 sample in each individual

Actual sample size in each individual: **1**

Erectile function

## **Randomization (investigator's opinion)**

Randomized

## **Randomization description**

Patients were randomly divided into two groups. Simple randomization was performed. Randomization unit was individual. For allocation of the participants, a computer-generated list of random numbers was used. Since patients underwent general anesthesia, they were not aware of the device being used for ligating posterior bladder pedicle. Blinding of the surgeon was not feasible. Data regarding erectile function before and after the surgery was collected and analyzed by researchers blinded to the intervention performed.

## **Blinding (investigator's opinion)**

Double blinded

## **Blinding description**

The patients were unaware of how the posterior bladder pedicle is closed. The researcher was blinded to the procedure by which the participants were underwent. The main surgeon was aware of the method of pedicle closure and blinding was not feasible.

## **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**

Hezarjarib St.

## **City**

Isfahan

## **Province**

Isfahan

## **Postal code**

8168814193

## **Approval date**

2016-09-27, 1395/07/06

## **Ethics committee reference number**

IR.mui.REC.1395.3.516

## **Health conditions studied**

### **1**

#### **Description of health condition studied**

Bladder cancer

#### **ICD-10 code**

C67

#### **ICD-10 code description**

Malignant neoplasm of bladder

### **2**

#### **Description of health condition studied**

Erectile dysfunction

#### **ICD-10 code**

N52

#### **ICD-10 code description**

Male erectile dysfunction

## **Primary outcomes**

### **1**

#### **Description**

Erectile function score in International Index of Erectile Function (IIEF) questionnaire

#### **Timepoint**

Before intervention, 6 and 12 months after intervention

#### **Method of measurement**

International Index of Erectile Function (IIEF)

## **Secondary outcomes**

empty

## **Intervention groups**

### **1**

#### **Description**

In this group, endo GIA stapling device was used to ligate bladder vascular pedicles. After developing plane between rectum and bladder at posterior aspect and freeing retzius space at lateral aspects, bladder pedicles are exposed and ligated using 60 mm endo GIA stapling

device, which is a non-absorbable stapler. The only difference between two intervention groups is the technique of bladder pedicle ligation.

**Category**

Treatment - Surgery

**2****Description**

In this group, LigaSure was used to ligate bladder vascular pedicles. After developing plane between rectum and bladder at posterior aspect and freeing retzius space at lateral aspects, bladder pedicles are exposed and ligated using LigaSure, which is a bipolar electrocoagulation system. The only difference between two intervention groups is the technique of bladder pedicle ligation.

**Category**

Treatment - Surgery

**Recruitment centers****1****Recruitment center****Name of recruitment center**

Al-Zahra Hospital

**Full name of responsible person**

Farshad Gholipour

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**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Esfahan University of Medical Sciences

**Full name of responsible person**

Shaghayegh Haghjooy Javanmard

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**Web page address**

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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**

Farshad Gholipour

**Position**

Resident

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Urology

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Resident

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## Person responsible for updating data

**Contact**  
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**Full name of responsible person**  
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## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**  
Undecided - It is not yet known if there will be a plan to make this available  
**Study Protocol**  
Yes - There is a plan to make this available  
**Statistical Analysis Plan**  
Yes - There is a plan to make this available  
**Informed Consent Form**  
Yes - There is a plan to make this available  
**Clinical Study Report**  
Yes - There is a plan to make this available  
**Analytic Code**  
Yes - There is a plan to make this available  
**Data Dictionary**  
Not applicable  
**Title and more details about the data/document**  
No more data  
**When the data will become available and for how long**  
No more data  
**To whom data/document is available**  
No more data  
**Under which criteria data/document could be used**  
No more data  
**From where data/document is obtainable**  
Farshad Gholipour, 09141286327, f-gholipour@student.tums.ac.ir  
**What processes are involved for a request to access data/document**  
Sending E-mail or contacting phone number  
**Comments**