

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

18 Sep 2026

### Use of only one catheter & eliminate cystostomy and internalized ureteral catheter after radical cystectomy & orthotopic neobladder formation with syncronize use of sandostatin

#### Protocol summary

##### Summary

The objective of this study is to evaluate long acting Sandostatin effects on reducing mucus after radical cystectomy surgery and neobladder formation with using only one urethral catheter and removal of suprapubic catheter (that used in usual surgical technique) and internalizing ureter catheters. A total of twenty patients with muscle invasive bladder cancer without urethral involvement will undergo radical cystectomy and neobladder formation. Instead of the usual operation, we eliminate suprapubic catheter in these people and internalize ureter catheters and randomly allocate into the following groups. For patients in one group, long acting Sandostatin is injected, deeply intramuscularly, two weeks before at the day of surgery. The patients in another group won't receive any drug. The mucus volume, incidence and the number of bladder washings during hospitalization will be compared between groups.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201101025527N1**  
Registration date: **2011-02-03, 1389/11/14**  
Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2011-02-03, 1389/11/14

##### Registrant information

##### Name

Hamidreza Zia

##### Name of organization / entity

Isfahan University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 311625555

##### Email address

hamidzia@resident.mui.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Isfahan University of Medical Sciences

##### Expected recruitment start date

2009-11-22, 1388/09/01

##### Expected recruitment end date

2011-03-21, 1390/01/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Use of only one catheter & eliminate cystostomy and internalized ureteral catheter after radical cystectomy & orthotopic neobladder formation with syncronize use of sandostatin

##### Public title

Sandostatin uses in orthotopic ileal neobladder

##### Purpose

Other

##### Inclusion/Exclusion criteria

Inclusion criteria: invasive bladder carcinoma, no urethral involvement, patient consent to perform surgery in this manner Exclusion criteria: urethral involvement in frozen section

##### Age

No age limit

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

No information

**Sample size**

Target sample size: 20

**Randomization (investigator's opinion)**

Randomized

**Randomization description****Blinding (investigator's opinion)**

Single blinded

**Blinding description****Placebo**

Not used

**Assignment**

Single

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Isfahan University of Medical Sciences

**Street address**

Isfahan University of Medical Science, hezar jirib street

**City**

Isfahan

**Postal code****Approval date**

2009-11-09, 1388/08/18

**Ethics committee reference number**

187140

**Health conditions studied****1****Description of health condition studied**

bladder cancer

**ICD-10 code**

C67

**ICD-10 code description**

Malignant neoplasm of bladder

**Primary outcomes****1****Description**

24-hour urine Mucous volume

**Timepoint**

on days seven and twenty one after surgery

**Method of measurement**

24-hour urine was collected and its mucus volume in gram was recorded

**Secondary outcomes****1****Description**

The number of washings

**Timepoint**

every 2 hours

**Method of measurement**

if urine flow become slow or urethral catheter blockage bladder irrigation is done &amp; number of washings was recorded

**2****Description**

Average time for drying of dressing

**Timepoint**

daily visit

**Method of measurement**

with daily visit and scale day from surgery

**Intervention groups****1****Description**

Intervention group: two doses (20 mg every doses and total 40 mg) deep intramuscular long acting Sandostatin two weeks before surgery and just before surgery. After cystectomy, a specimen from proximal part of urethral is taken and sent for Frozen section and if the specimen will negative, neobladder will created with 40 cm of ileum, internalized ureters catheters and use just only urethral Foley catheter. Routine neobladder washing was not done unless there was a slow urine flow or a urethral catheter blockage.

**Category**

Treatment - Drugs

**2****Description**

Control group: after cystectomy, a specimen from proximal part of urethral is taken and sent for Frozen section and if the specimen will negative, neobladder will created with 40 cm of ileum, internalized ureters catheters and use just only urethral Foley catheter. Routine neobladder washing was not done unless there was a slow urine flow or a urethral catheter blockage.

**Category**

Treatment - Surgery

**Recruitment centers****1****Recruitment center**

**Name of recruitment center**  
Alzahra hospital  
**Full name of responsible person**  
**Street address**  
**City**  
Isfahan

**Web page address**

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**  
Isfahan University of Medical Sciences  
**Full name of responsible person**  
Mohammad Hatef Khorrami  
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## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**  
Vice Chancellery of Research of Isfahan University of Medical Sciences  
**Full name of responsible person**  
Zahra Fallah  
**Street address**  
Bulding NO 4, Isfahan University of Medical Sciences, Hezar jerib street  
**City**  
Isfahan  
**Grant name**  
**Grant code / Reference number**  
**Is the source of funding the same sponsor organization/entity?**  
Yes

#### Title of funding source

Vice Chancellery of Research of Isfahan 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

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**Full name of responsible person**  
Hamidreza Zia  
**Position**  
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## Person responsible for updating data

### Contact

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## 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*