

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)

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+98 311625555

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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 & 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

Position

MD, urologist

Other areas of specialty/work

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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

Name of organization / entity

Isfahan University of Medical Sciences

Full name of responsible person

Hamidreza Zia

Position

Resident of urology

Other areas of specialty/work

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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