

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Evaluation of the effect of diluted intravesical bupivacaine on the urinary catheter related bladder discomfort during recovery from anesthesia in young males

Protocol summary

Summary

Bladder discomfort due to urinary catheter is one of the most common reasons of patient's agitation in the recovery room after operations. This complication especially is more obvious in young male patients. So the importance of this complication and relative short-coming of previous protective and therapeutic modalities, in a prospective randomized double blinded clinical trial we intend to use a diluted local anesthetic drug "Bupivacaine", infused directly into bladder via urinary catheter, for evaluating whether this drug is able to reduce that complication or not? In this study we will use 54 male patients with 18-60 years old, witch candidate for non-pelvic surgeries under general anesthesia and need urinary catheterization during his operations. Cases will elected from ASA physical class I & II and selected patients must be without kidney and urinary tract disease, prostate hypertrophy and also overactive bladder symptoms. After induction of anesthesia, patients will be catheterized with a NO: 16 folly catheter by using 2% lidocaine lubricant gel, and its cuff will inflate with 10 ml of distilled water. Fifteen min before the termination of the surgery, in control group 50 ml of normal saline, and in the intervention group 50 ml of 0.2% bupivacaine will be infused into bladder via urinary catheter and then catheter will clamped for 30 min. After that in the recovery room, patients will be evaluated for occurrence of agitation and intensity of bladder discomfort related to catheter every 15 min until 1 hour by using "Likert Scale". Also the dose of fentanyl and midazolam used for treatment of these complications will be recorded and compared statistically between two groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014090111398N6**

Registration date: **2014-09-23, 1393/07/01**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2014-09-23, 1393/07/01

Registrant information

Name

Mohammad Reza Ghodrati

Name of organization / entity

Iran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 8894 6762

Email address

m-ghodrati@tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Research deputy of Iran University of Medical Sciences

Expected recruitment start date

2014-10-01, 1393/07/09

Expected recruitment end date

2015-03-31, 1394/01/11

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effect of diluted intravesical bupivacaine on the urinary catheter related bladder discomfort during recovery from anesthesia in young males	
Public title	Effect of intravesical bupivacaine on the urinary catheter related bladder discomfort
Purpose	Prevention
Inclusion/Exclusion criteria	Inclusion criteria: male gender, 18-60 years old, candidated for surgery under general anesthesia, having indication for urinary catheter insertion, ASA physical class I & II, and agreement for participation in the study Exclusion criteria: female gender, age less than 18 and more than 60, no indication for bladder catheterization during surgery, ASA class more than II, no agreement for participation, addiction to opiates and other drugs abusers, patients with kidney and urinary tract diseases and intra pelvic & lower abdomen surgeries.
Age	From 18 years old to 59 years old
Gender	Male
Phase	2-3
Groups that have been masked	No information
Sample size	Target sample size: 54
Randomization (investigator's opinion)	Randomized
Randomization description	
Blinding (investigator's opinion)	Double blinded
Blinding description	
Placebo	Used
Assignment	Parallel
Other design features	
Secondary Ids	empty
Ethics committees	
<u>1</u>	
Ethics committee	
Name of ethics committee	Iran University of Medical Sciences
Street address	Hemmat highway, between Sheykhfazlollah and Chamran
City	Tehran
Postal code	
Approval date	2014-05-20, 1393/02/30

Ethics committee reference number	24713- 103614
Health conditions studied	
<u>1</u>	
Description of health condition studied	Urinary catheter related bladder discomfort
ICD-10 code	T19.1
ICD-10 code description	Foreign body in bladder
Primary outcomes	
<u>1</u>	
Description	Severity of patient's bladder discomfort in recovery
Timepoint	Every 15 min after arrival of patients to recovery until 30 min
Method of measurement	Patient's own report and question from them
<u>2</u>	
Description	Severity of patient's agitation
Timepoint	Every 15 min after arrival of patients to recovery until 30 min
Method of measurement	Observation by recovery room nurse
Secondary outcomes	
<u>1</u>	
Description	Amount of fentanyl usage
Timepoint	Discharge time from recovery
Method of measurement	Sum of the drug usage
Intervention groups	
<u>1</u>	
Description	In intervention group: Infusion of 50 ml Bupivacaine 0.2% into bladder via urinary catheter 15 min before awakening from anesthesia
Category	Prevention
<u>2</u>	
Description	

In control group: Infusion of 50 ml normal saline as placebo into bladder via urinary catheter 15 min before awakening from anesthesia

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Firoozgar Hospital

Full name of responsible person

Mohammad Reza Ghodrati

Street address

Anesthesiology department, Firoozgar hospital, Beh-afarin St, Karim Khan Av.

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Deputy of Research & technology, Iran University of Medical Sciences

Full name of responsible person

Seyed Ali Javad Moosavi MD.

Street address

Department of Internal Medicine, Hazrat-E-Rasoul Hospital, Iran University of Medical Sciences, Niayesh St., Sattarkahn Ave

City

Tehran

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Deputy of Research & technology, Iran 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

Iran University of Medical Sciences

Full name of responsible person

Mohammad Reza Ghodrati MD.

Position

Anesthesiologist, Assistant professor

Other areas of specialty/work

Street address

Anesthesiology Department, Firoozgar Hospital, Beh-afarin St, Karim Khan Av.

City

Tehran

Postal code

Phone

+98 21 8894 6762

Fax

Email

mrghodrati@yahoo.comghodrati.mr@iums.ac.ir

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Mohammad Reza Ghodrati

Position

Anesthesiologist, Assistant Professor

Other areas of specialty/work

Street address

Anesthesiology Department, Firoozgar Hospital, Beh-afarin St, Karim Khan Av.

City

Tehran

Postal code

Phone

+98 21 8894 6762

Fax

Email

mrghodrati@yahoo.comghodrati.mr@iums.ac.ir

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Iran University of Mwdical Sciences

Full name of responsible person

Mohammad Reza Ghodrati MD.

Position

Anesthesiologist

Other areas of specialty/work

Street address

City

Postal code

Phone

00

Fax

Email

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