

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

28 May 2026

### Effectiveness comparison of epidural Dexmedetomidine vs Ropivacaine infusion to prevent erection following reconstructive urethral surgery

#### Protocol summary

Registration timing: **registered\_while\_recruiting**

#### Study aim

The effect of epidural infusion of Dexmedetomidine and Ropivacaine on erection following reconstructive urethral surgery

Last update: **2020-08-23, 1399/06/02**

Update count: **0**

#### Registration date

2020-08-23, 1399/06/02

#### Design

Candidate patients for reconstructive urethral surgery were divided into two groups using computer generated simple randomization and random number generation software and each group includes 15 individuals. Groups; Dexmedetomidine group and the Ropivacaine group. Sample size 30 was determined and divided into 2 groups. Sample size 30 was determined that divided in 2 groups. Double blind Clinical trial.

#### Registrant information

##### Name

Nima saeedi

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 2641 8939

##### Email address

nimasaeedi@sbmu.ac.ir

#### Settings and conduct

all Patients candidate who fulfilled inclusion criteria for reconstructive urethral surgery in Shohadaye Tajrish Hospital divided in groups and participants have no consent about groups and medication which they received.

#### Recruitment status

**Recruitment complete**

#### Funding source

#### Participants/Inclusion and exclusion criteria

All patients between 20-60 years old candidate for reconstructive urethral surgery Without history of cardiac disease ( Syncope, Arrhythmia and bradycardia)

#### Expected recruitment start date

2020-08-10, 1399/05/20

#### Expected recruitment end date

2020-12-20, 1399/09/30

#### Intervention groups

Two groups; The first group receive Dexmedetomidine through epidural continuous infusion pump and the second group receive Ropivacaine through epidural continuous infusion pump.

#### Actual recruitment start date

empty

#### Actual recruitment end date

empty

#### Main outcome variables

The effect of epidural Dexmedetomidine and Ropivacaine infusion on erection incidence

#### Trial completion date

empty

#### General information

#### Scientific title

Effectiveness comparison of epidural Dexmedetomidine vs Ropivacaine infusion to prevent erection following reconstructive urethral surgery

#### Reason for update

#### Acronym

#### IRCT registration information

IRCT registration number: **IRCT20190131042569N4**

Registration date: **2020-08-23, 1399/06/02**

#### Public title

The effect of epidural infusion of Dexmedetomidine and Ropivacaine on erection following reconstructive urethral

surgery

**Purpose**  
Treatment

**Inclusion/Exclusion criteria**  
**Inclusion criteria:**  
All patients between 20-60 years old candidate for reconstructive urethral surgery  
**Exclusion criteria:**  
History of cardiac disease ( Syncope, Arrhythmia and bradycardia) History of allergic reaction to drug which is used in the study

**Age**  
From **20 years** old to **60 years** old

**Gender**  
Male

**Phase**  
3

**Groups that have been masked**

- Participant
- Care provider
- Outcome assessor

**Sample size**  
Target sample size: **30**

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

**Randomization description**  
Using computer generated simple randomization (random number generator software) to design two groups (dexmedetomidine vs ropivacaine)

**Blinding (investigator's opinion)**  
Double blinded

**Blinding description**  
Due to the fact that patients in both groups have epidural catheters and do not know which drug is used, they are blind. The anesthesiologist in charge is not aware of the patient's group and drugs that is used in infusion pump . And the person responsible for follow-up and recordings data has no information about the patient's group and only the person responsible for preparing epidural infusion pump is aware of the patient's groups.

**Placebo**  
Not used

**Assignment**  
Parallel

**Other design features**

## Secondary Ids

empty

## Ethics committees

1

**Ethics committee**  
**Name of ethics committee**  
Ethics committee of Shahid Beheshti University of Medical Sciences  
**Street address**

Shahid Beheshti University of Medical Science, Arabi Ave., Daneshjoo Blvd., Velenjak, Tehran

**City**  
Tehran

**Province**  
Tehran

**Postal code**  
1985717443

**Approval date**  
2020-08-09, 1399/05/19

**Ethics committee reference number**  
IR.SBMU.RETECH.REC.1399.473

## Health conditions studied

1

**Description of health condition studied**

Erection

**ICD-10 code**

**ICD-10 code description**

## Primary outcomes

1

**Description**

Erection after the reconstructive urethral surgery

**Timepoint**

Daily for one week

**Method of measurement**

Questionnaire (quality and degree of erection)

## Secondary outcomes

empty

## Intervention groups

1

**Description**

Intervention group 1: At the end of operation, the continuous infusion pump with a total volume of 100 cc containing dexmedetomidine 50 micro grams and sterile water; 6 cc per hour is connected to the epidural catheter.

**Category**

Prevention

2

**Description**

Intervention group 2: At the end of the operation, the continuous infusion pump with a total volume of 100 cc containing Ropivacaine 0.125% and sterile water; 6 cc per hour is connected to the epidural catheter.

**Category**

Prevention

## Recruitment centers

1

### Recruitment center

**Name of recruitment center**

Shohadaye Tajrish Hospital

**Full name of responsible person**

Nima Saeedi

**Street address**

Shohadaye Tajrish Hospital, Tajrish Square, Tehran

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pr\_shohada@sbmu.ac.ir

## Sponsors / Funding sources

1

### Sponsor

**Name of organization / entity**

Research Department of Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Seyed Ali Ziayi

**Street address**

Third floor, School of Medicine, Shahid Beheshti University of medical science, Shahid Chamran Highway, Tehran

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mpd@sbmu.ac.ir

**Web page address****Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Research Department of Shahid Beheshti 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**

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Nima Saeedi

**Position**

Anesthesia assistance

**Latest degree**

Specialist

**Other areas of specialty/work**

Anesthesiology

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## Person responsible for scientific inquiries

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**Latest degree**

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**Other areas of specialty/work**

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## Person responsible for updating data

### Contact

**Name of organization / entity**

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Nima Saeedi

**Position**

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**Latest degree**

Medical doctor

**Other areas of specialty/work**

Anesthesiology

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## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**

Yes - There is 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**

Yes - There is a plan to make this available

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

Participant data (age, grade of erection and type of patient's group) are to be shared.

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

1 year after publication

**To whom data/document is available**

Researchers working in academic institutions

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

Using data and analysis for use in academic research

**From where data/document is obtainable**

Send an Email to Dr.Nima Saeedi, Email Address:  
nimasaeeedi7@yahoo.com

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

Send request via Email and after 1 week will be replied.

**Comments**