Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Comparison of multimodal analgesia and opioid based method in urethral reconstruction surgery

Protocol summary

Study aim
Investigating the effect of multimodal analgesia on the amount of perioperative narcotics consumption in urethral reconstruction surgery

Design
A clinical trial with 2 groups, with parallel groups, double blind, randomized, phase 3 on 30 patients. For randomization, a simple randomization method is used using a table of random numbers.

Settings and conduct
After the approval of the ethics committee and obtaining the consent of the patients, 30 candidates for urethral repair surgery of Shahada Tajrish Hospital who meet the entry criteria will be included in the study. Patients are assigned to one of the two groups by simple randomization. Individuals responsible for randomization from the research team will not be responsible for examining the dependent variable. The data analyst will not know about the coding of the groups.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Patients who are candidates for urethral reconstruction treatment with normal mental status and adherence to the treatment plan, who have an ASA score I or II with normal lab tests. Exclusion criteria: Having an addiction to drugs or psychotropic substances

Intervention groups
The intervention group (M) is treated with gabapentin and clonidine drugs before surgery, and during surgery, patients are given dexamethasone, magnesium infusion, pudendal nerve block, and ropivacaine injection to remove buccal mucosa. Ketorolac and intravenous acetaminophen will be used at the end of the procedure. The control group (S) will only use the standard method of drug treatment with opioids and placebo tablets and solution will be used before and during the operation.

Main outcome variables
Perioperative opioid consumption

General information

Reason for update
Updating the actual time of sampling and the realized sample size

Acronym

IRCT registration information
IRCT registration number: **IRCT20230204057318N3**
Registration date: **2023-11-20, 1402/08/29**
Registration timing: **prospective**

Last update: **2026-08-01, 1405/05/10**
Update count: **1**

Registration date
2023-11-20, 1402/08/29

Registrant information

Name
Alireza Shakeri

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 21 7343 0000

Email address
dr.alirezashakeri@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-11-22, 1402/09/01

Expected recruitment end date
2024-05-21, 1403/03/01

Actual recruitment start date
2023-12-06, 1402/09/15

Actual recruitment end date
2025-12-06, 1404/09/15

Trial completion date
empty

Scientific title
Comparison of multimodal analgesia and opioid based method in urethral reconstruction surgery

Public title
Comparison of multimodal analgesia and opioid based method

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Patient candidate for urethral reconstruction treatment Mental health and providing informed consent Ability to adhere to patient visit schedule and other relevant protocols American Society of Anesthesiologist (ASA) score I or II Normal kidney and liver function

Exclusion criteria:
Any condition that prevents obtaining informed consent. Any other disease, including malignancy, abnormal laboratory tests, psychiatric disease, which in the opinion of the researcher prevents the patient from adhering to the study. Concomitant or uncontrolled illness that, in the researcher's opinion, causes harm to the patient or non-adherence to the study. History of drug addiction, psychoactive drugs and other illegal drug substances

Age
From **18 years** old

Gender
Male

Phase
3

Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **30**
Actual sample size reached: **40**

Randomization (investigator's opinion)
Randomized

Randomization description
For randomization, a simple randomization method was used using a table of random numbers and through the Random generator program of the Android version. In this randomization, patients who meet the criteria for entering the study are assigned a number before anesthesia, which will represent one of the two study groups.

Blinding (investigator's opinion)
Double blinded

Blinding description
The patients, the person responsible for data collection, and the data analyzer will be unaware of how the groups are coded. Only the anesthesiologist in charge of the patient will know about the patient group, but the attending physician will not.

Placebo
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
Yaman st., Shahid Chamran Hwy.

City
Tehran

Province
Tehran

Postal code
1985717443

Approval date
2023-10-29, 1402/08/07

Ethics committee reference number
IR.SBMU.RETECH.REC.1402.419

Health conditions studied

1

Description of health condition studied
Urethral reconstruction surgery

ICD-10 code
N35

ICD-10 code description
Urethral stricture

Primary outcomes

1

Description
Perioperative opioid consumption (intraop + postop)

Timepoint
intraoperative and postoperative

Method of measurement
Based on the amount of narcotics used and recorded in the patient's file

Secondary outcomes

1

Description
Intraoperative opioid consumption

Timepoint
Intraoperative

Method of measurement
Patient file information

2

Description
Postoperative opioid consumption
Timepoint
Postoperative up to 24h
Method of measurement
Patient file information

3

Description
Postoperative pain
Timepoint
Postoperative up to 24h
Method of measurement
VAS score

4

Description
Hospitalization days after surgery
Timepoint
Postoperative
Method of measurement
Hospitalization days

5

Description
Postoperative complications (nausea, vomiting, constipation)
Timepoint
Postoperative
Method of measurement
Observation/questionnaire

6

Description
Intraoperative hemodynamic (HR, MAP)
Timepoint
Intraoperative
Method of measurement
Hemodynamic monitoring

Intervention groups

1

Description
Intervention group (M): One hour before patients enter the operating room, in group M, a dose of clonidine with a dose of 3 microgram/kg and a dose of gabapentin with a dose of 4 mg/kg will be given orally to the patients. Patients of both groups are put under general anesthesia in the same way. In group M, a dose of dexamethasone with a dose of 8 mg will be prescribed after the start of anesthesia. After the start of anesthesia and before the start of surgery for patients in group M, a bilateral pudendal nerve block will be performed with 10 ml of 0.5% ropivacaine under ultrasound guidance. During surgery for group M, magnesium sulfate infusion will be continued with an initial dose of 30mg/kg and then 15mg/kg/h until the end of the surgery. In order to remove the buccal graft, at the end of the work in group M, 0.25% bupivacaine solution with a volume of 10 mL will be used. At the end of the surgery in group M, a dose of intravenous ketorolac with a dose of 30 mg and a dose of intravenous paracetamol with a dose of one gram will be used.
Category
Treatment - Drugs

2

Description
Control group (S): One hour before the patients enter the operating room, two placebo tablets will be given to the patients orally in the S group. Patients of both groups are put under general anesthesia in the same way. In group S, 2 ml of normal saline (placebo) will be administered after the start of anesthesia. During surgery for group S, normal saline infusion will be used as a placebo until the end of surgery. To perform buccal graft removal, at the end of the work in group S, normal saline solution with a volume of 10 mL will be used. At the end of surgery in group S, morphine with a dose of 0.05mg/kg will be used intravenously.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Shohadaye Tajrish Hospital
Full name of responsible person
Hamidreza Azizi Farsani
Street address
Quds Square, Shahrdari Street, Shohadaye Tajrish Hospital
City
Tehran
Province
Tehran
Postal code
989934148
Phone
+98 21 2271 8000
Fax
+98 21 2271 2241
Email
lib.shmc@sbmu.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person

Afshin Zarghi

Street address

Shahid Beheshti University of Medical Sciences, Next to Taleghani Hospital, Yemen Street, Shahid Chamran Highway, Tehran, Iran

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1983963113

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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

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

Alireza Shakeri

Position

Assistant professor

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

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Email

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Person responsible for scientific inquiries

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Full name of responsible person

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Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

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Alireza Shakeri

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

There is no more information

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available