Clinical Trial Protocol
Iranian Registry of Clinical Trials

04 Jul 2026

Evaluation of efficacy and safety of furosemide in transurethral prostate resection in reducing postoperative hyponatremia : a randomized controlled trial

Protocol summary

Study aim
Determining of efficacy and safety of furosemide in transurethral prostate resection in reducing postoperative hyponatremia

Design
Clinical trial with control group, with parallel groups, triple-blinded, randomized, phase 2 on 70 patients. WWW.randomizer.org was used for randomization.

Settings and conduct
The present study is an interventional triple-blinded clinical trial (the patient, the data collector and the data analyzer were blinded). The community is the patients who undergoing TURP (Transurethral resection of the prostate) in Isfahan's medical-educational centers in year 2022. In the intervention group, they will receive 40 milligrams furosemide intravenously before the anesthesia induction. The control group will not receive this drug. Then sodium, potassium, chlorine and creatinine levels before surgery, one hour after surgery and 24 hours after surgery will be evaluated.

Participants/Inclusion and exclusion criteria
Patients who have standard indications of the TURP and have normal renal function

Intervention groups
In the intervention group, they will receive 40 milligrams furosemide intravenously before the anesthesia induction. The control group will not receive this drug.

Main outcome variables
Sodium, potassium, chlorine and creatinine levels before surgery, one hour after surgery and 24 hours after surgery

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20211208053328N2**
Registration date: **2022-07-30, 1401/05/08**
Registration timing: **prospective**

Last update: **2022-07-30, 1401/05/08**
Update count: **0**

Registration date
2022-07-30, 1401/05/08

Registrant information

Name
Hossein Bahrami Samani

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 31 3620 2020

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bahrami.hossein1993@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-08-06, 1401/05/15

Expected recruitment end date
2023-01-20, 1401/10/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Evaluation of efficacy and safety of furosemide in transurethral prostate resection in reducing postoperative hyponatremia : a randomized controlled

trial

Public title
Evaluation of efficacy and safety of furosemide in transurethral prostate resection in reducing postoperative hyponatremia : a randomized controlled trial
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria:
Patients have standard indication for TURP (Transurethral resection of the prostate)(frequent urinary retention, bilateral hydronephrosis with the probability of kidney damage, frequent urinary tract infection because of high post-void residual, Gross and severe hematuria, severe urinary symptoms in BPH (benign prostatic hyperplasia) that is resistant to treatment) Normal renal function (Normal blood urea nitrogen and creatinine)
Exclusion criteria:
Age
No age limit
Gender
Male

Phase
2
Groups that have been masked

- Participant
- Investigator
- Data analyser

Sample size
Target sample size: **70**
Randomization (investigator's opinion)
Randomized
Randomization description
Patients will be randomly in the case or control group by www.randomizer.org, so that the patient's number between 70 patients will be in the two categories, including category 1 as the case group and the 2 as the control group. Then, based on the order of the operation and categorization, these patients will be in one of these groups.
Blinding (investigator's opinion)
Triple blinded
Blinding description
The patient will be blinded in terms of the drug administration. Envelopes including the study group, will be given to the anesthesiologist outside of the operating room before the anesthesia induction so that the drug can be injected if the patient was in the relevant group. The data collector is not aware of it, so he will be blinded. The data analyzer will not be aware of the study group.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Isfahan University of Medical Sciences
Street address
Vice Chancellor for Research and Technology, Building No. 4, Isfahan University of Medical Sciences and Health Services, Hezar Jerib St.
City
Isfahan
Province
Isfehan
Postal code
8174673461
Approval date
2022-03-31, 1401/01/11
Ethics committee reference number
IR.MUI.MED.REC.1401.002

Health conditions studied

1

Description of health condition studied
Hyponatremia after TURP surgery
ICD-10 code
Z48. 816
ICD-10 code description
Encounter for surgical aftercare following surgery on the genitourinary system

Primary outcomes

1

Description
Sodium level of the serum
Timepoint
Before surgery, one hour after surgery and 24 hours after surgery
Method of measurement
Audicom AC9800 Automatic Electrolyte Analyzer

Secondary outcomes

1

Description
Potassium level of the serum
Timepoint
Before surgery, one hour after surgery and 24 hours after surgery
Method of measurement
Audicom AC9800 Automatic Electrolyte Analyzer

2

Description
Creatinine level of the serum
Timepoint
Before surgery, one hour after surgery and 24 hours after surgery
Method of measurement
Creatinin Jaffe kit, Biorexfars company

Intervention groups

1

Description
Intervention group: Immediately before the anesthesia induction, they will receive intravenous 40 mg of furosemide (Ampule Lasix, 40mg/4ml, Sanofi, India). This group also receives the necessary anesthetic measures as routine.
Category
Treatment - Other

2

Description
Control group: Without Furosemide (Ampule Lasix, 40mg/4ml, Sanofi, India). This group receives the necessary anesthetic measures as routine.
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Alzahra Hospital
Full name of responsible person
Hossein Bahrami Samani
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2

Recruitment center
Name of recruitment center
Khorshid Hospital
Full name of responsible person
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Sponsors / Funding sources

1

Sponsor
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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
Esfahan 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
Esfahan University of Medical Sciences
Full name of responsible person
Hossein Bahrami Samani
Position
Resident

Latest degree
Medical doctor
Other areas of specialty/work
Urology
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Person responsible for updating data

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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
Information is kept confidential
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
No - There is not 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
Yes - There is 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
Not applicable
Title and more details about the data/document
Information about the main outcome can be shared
When the data will become available and for how long
After publishing the results
To whom data/document is available
Researchers working in academic and scientific institutions
Under which criteria data/document could be used
Using data to complete studies
From where data/document is obtainable
Dr. Hossein Bahrami Samani, Isfahan University of Medical Sciences
What processes are involved for a request to access data/document
By examining the researcher's request and providing sufficient documentation of his research and the reason for using the data can be provided
Comments