

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 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

Isfahan

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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Recruitment center

Name of recruitment center

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Full name of responsible person

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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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
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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