Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Comparison of the effect of irrigation fluid at room temperature with irrigation fluid to body temperature on hypothermia and other intraoperative and postoperative outcomes in patients undergoing transurethral resection of prostate (TURP) under spinal anesthesia

Protocol summary

Study aim
Determination of the effect of irrigation fluid temperature on hypothermia and other intraoperative and postoperative outcomes in patients undergoing transurethral resection of prostate (TURP) under spinal anesthesia

Design
Phase 3 clinical trial with control group, with parallel groups, double-blind, randomized by block randomization method with blocks of size 4 with a ratio of 1 to 1 (as two groups A and B), with a sample size of 76 patients

Settings and conduct
The study will be performed in the urology operating room of Razi Hospital in Rasht. The study will be double blind in which neither the patient nor the researcher responsible for completing the questionnaires is aware of the type of serum allocated to surgery.

Participants/Inclusion and exclusion criteria
Inclusion criteria: having ASA class I, II; age between 40 to 75 years; body mass index between 18 to 30; duration of operation less than 2 hours. Exclusion criteria: patients with active infection; taking antipyretic drugs within 24 hours before surgery; neuropathy; thyroid dysfunction; peripheral vascular disease, severe skin lesions or allergies; contraindications spinal anesthesia; history of ACEI or CCB

Intervention groups
Intervention group 1: Using irrigation fluid warmed to body temperature (37 degrees). Control group: Using irrigation fluid at room temperature.

Main outcome variables
Hypothermia

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20121216011766N6**
Registration date: **2021-01-09, 1399/10/20**
Registration timing: **registered_while_recruiting**

Last update: **2021-01-09, 1399/10/20**
Update count: **0**

Registration date
2021-01-09, 1399/10/20

Registrant information

Name
Hossein Khoshrang

Name of organization / entity
Guilan University of Medical Sciences

Country
Iran (Islamic Republic of)

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khoshrang@gums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-12-12, 1399/09/22

Expected recruitment end date
2021-10-14, 1400/07/22

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison of the effect of irrigation fluid at room temperature with irrigation fluid to body temperature on hypothermia and other intraoperative and postoperative outcomes in patients undergoing transurethral resection of prostate (TURP) under spinal anesthesia

Public title
Effect of irrigation fluid temperature on hypothermia and other outcomes of anesthesia

Purpose
Supportive

Inclusion/Exclusion criteria

Inclusion criteria:
All patients candidate for elective transurethral prostatectomy under spinal anesthesia The ASA Physical Status Classification I,II (normal healthy patient or patient with mild systemic disease) Age between 40 to 75 years Body mass index (BMI) more than 18 and less than 30 kg/m2 Operating time less than 2 hours

Exclusion criteria:
Active infection taking antipyretic drugs within 24 hours before surgery neuropathy thyroid dysfunction or thyroid hormone use peripheral vascular disease skin lesions or history of severe skin contact allergies contraindications to spinal anesthesia history of ACEI or CCB use due to impaired self-regulatory mechanism of the patient's body temperature history of bleeding disorders history of taking anticoagulants

Age
From **40 years** old to **75 years** old

Gender
Male

Phase
N/A

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size
Target sample size: **76**

Randomization (investigator's opinion)
Randomized

Randomization description
Block randomization with blocks of size 4 with a ratio of 1 to 1 (as two groups A and B) via a online program named sealed envelop/randomisation

Blinding (investigator's opinion)
Double blinded

Blinding description
One of the researchers (anesthesia resident) will allocate serums to patients in two groups A (serum at room temperature) and B (serum heated to body temperature 37 degrees) based on a table prepared from random blocks. Neither the patient nor the evaluator is aware of the type of serum assigned to the surgery. At the top of the checklist which be completed for each patient, the group type (A or B) will be recorded.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Guilan University of Medical Sciences

Street address
Razi Hospital, Sardar Jangal street

City
Rasht

Province
Guilan

Postal code
41448-95655

Approval date
2020-10-07, 1399/07/16

Ethics committee reference number
IR.GUMS.REC.1399.322

Health conditions studied

1

Description of health condition studied
Hypothermia

ICD-10 code
T88.51

ICD-10 code description
Hypothermia following anesthesia

Primary outcomes

1

Description
Hypothermia

Timepoint
Upon arrival of the patient in the operating room, at the beginning of the operation, 30 minutes after the start of the operation, at the end of the operation, in the recovery

Method of measurement
The tympanic method means placing a thermometer in the patient's ear and monitoring the temperature during surgery

Secondary outcomes

1

Description
Heart rate

Timepoint
Heart rate are recorded every 5 minutes during surgery.
Method of measurement
Register in the checklist

2

Description
Blood pressure
Timepoint
Blood pressure are recorded every 5 minutes during surgery
Method of measurement
Register in the checklist

3

Description
Hemoglobin
Timepoint
Hemoglobin is checked before and after surgery through a blood test.
Method of measurement
Register in the checklist

4

Description
The amount of transfusion
Timepoint
The amount of transfusion will also be recorded in the operating room.
Method of measurement
Register in the checklist

5

Description
Recovery time
Timepoint
The recovery time is recorded in the patient file in the operating room.
Method of measurement
Register in the checklist

6

Description
Hospital stay
Timepoint
The hospital stay is calculated on the day of discharge.
Method of measurement
Register in the checklist

Intervention groups

1

Description
Intervention group: Irrigation fluid (normal saline 0.9%) warmed to body temperature (37 degrees) using boiler device (made in Iran, sazgar steam (sazgarmed), with a capacity of 9 serums 35 * 30 * 30) to the required number, which varies for each patient depending on individual characteristics and operation time
Category
Treatment - Devices

2

Description
Control group: Irrigation fluid (normal saline 0.9%) with room temperature (between 21 and 23 degrees)
Category
Treatment - Devices

Recruitment centers

1

Recruitment center
Name of recruitment center
Razi Hospital
Full name of responsible person
Hossein Khoshang
Street address
Sardar-e-Jangal street
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Urology Research Center, Guilan University of Medical Sciences
Full name of responsible person
Siavash Falahatkar
Street address
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urc@gums.ac.ir
Grant name

10506

Grant code / Reference number

32

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

Yes

Title of funding source

Urology Research Center, Guilan 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

Guilan University of Medical Sciences

Full name of responsible person

Mohammad Sadegh Foroughifar

Position

Anesthesia resident

Latest degree

Medical doctor

Other areas of specialty/work

Anesthesiology

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

Hossein Khoshrang

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

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Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

Samaneh Esmaeili

Position

Non-faculty researcher

Latest degree

Master

Other areas of specialty/work

Urology

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

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

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

No - There is not a plan to make this available