

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 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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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 an 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

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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

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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
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Mohammad Sadegh Foroughifar
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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