Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Comparing Ondansetron, Pethidine, Dexmedetomidine as adjuant therapy to neuroaxial Marcaine 5% in postoperative shivering in patients undergoing TURP

Protocol summary

Study aim

Evaluation of the Effect of Adding Ondansetron, Pethidine, and Dexmedetomidine to 5% Marcaine via the Neuraxial Route in Controlling Shivering in Patients Undergoing TURP

Design

Parallel groups, double-blind, randomized design.Randomization will be performed using an online program available on www.sealedenvelope.com.

Settings and conduct

Methods This randomized clinical trial will include 81 TURP candidates referred to Vali-Asr and Amir al-Momenin Hospitals in Arak who meet the inclusion criteria. Patients will be randomly assigned into three equal groups receiving Ondansetron, Pethidine, or Dexmedetomidine. After IV line placement and confirmation of IV patency, patients will receive 5 mL/kg of crystalloid fluid as a compensatory volume expander. Spinal anesthesia will be administered using a B. Braun needle at the L4-L5 or L5-S1 space, and the study drugs, pre-prepared in 5 mL volumes, will be injected. Following surgery, patients will be transferred to the recovery room in the supine position. Vital signs, shivering score, pain score, pulse rate, MAP, and SpO_2 will be monitored and recorded by a blinded intern to ensure unbiased data collection.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: • Patients undergoing TURP referred to Vali-Asr and Amir al-Momenin Hospitals in Arak.

Exclusion Criteria: • Conversion to general anesthesia.

Intervention groups

Men aged 35 to 70 years who are candidates for TURP surgery.

Main outcome variables

Average shivering score of patients in recovery/Average MAP of patients in recovery

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20250112064367N1**
Registration date: **2025-02-06, 1403/11/18**
Registration timing: **prospective**

Last update: **2025-02-06, 1403/11/18**
Update count: **0**

Registration date

2025-02-06, 1403/11/18

Registrant information

Name

Fatemeh Akhavan malayeri

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 86 3224 2043

Email address

fateme.akhavan2021@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-03-21, 1404/01/01

Expected recruitment end date

2025-12-21, 1404/09/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Comparing Ondansetron, Pethidine, Dexmedetomidine as adjuant therapy to neuroaxial Marcaine 5% in postoperative shivering in patients undergoing TURP

Public title
The effect of ondansetron, pethidine, and dexmedetomidine on postoperative shivering.

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Patients undergoing TURP referred to Vali-Asr and Amir Al-Momenin Hospitals in Arak. Patients with informed consent for participation in the study. Patients aged 35 to 70 years Patients classified as ASA Class I and II Patients with no cardiovascular, respiratory, or renal diseases. Patients with no history of cerebrovascular accident (CVA). Patients who are not IV drug abusers All patients undergoing spinal anesthesia No allergy to Marcaine, Ondansetron, Pethidine, or Dexmedetomidine.

Exclusion criteria:
All patients for whom spinal anesthesia fails during surgery, requiring conversion to general anesthesia. All patients who experience cardiopulmonary arrest for any reason during surgery. All patients who, for any reason, require general anesthesia.

Age
From **35 years** old to **70 years** old

Gender
Male

Phase
2-3

Groups that have been masked

- Participant
- Outcome assessor

Sample size
Target sample size: **81**

Randomization (investigator's opinion)
Randomized

Randomization description
Patients are randomly assigned into three equal groups using a blocked randomization method with blocks of six. The random sequence is generated using an online program available on www.sealedenvelope.com. (https://www.sealedenvelope.com/) Allocation concealment is ensured using the opaque sealed envelope method.

Blinding (investigator's opinion)
Double blinded

Blinding description
The study will be conducted in a double-blind design. All patients will be randomly allocated into three equal groups using a block randomization method. Medications will be prepared and labeled as A, B, and C under the supervision of the principal investigator, with the preparation carried out by a trained anesthesia technician. The principal investigator will be aware of the group allocations. The intern, responsible for data collection and questionnaire completion, will remain blinded to the group assignments to ensure unbiased outcome assessment.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Arak University of Medical Sciences

Street address
Building 870, Deylami Ave, Azod Ave, Abbas Abbad Street, Arak

City
Arak

Province
Markazi

Postal code
3813663817

Approval date
2025-01-07, 1403/10/18

Ethics committee reference number
IR.ARAKMU.REC.1403.294

Health conditions studied

1

Description of health condition studied
postoperative shivering in patients undergoing TURP

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
The occurrence or absence of shivering in patients.

Timepoint
The occurrence of shivering and pain score in patients at 2, 4, 6, and 8 hours postoperatively.

Method of measurement
VAS questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Group 1:Patients will receive 75 mg of Bupivacaine (Exir Pharmaceutical, Iran) combined with 1–1.5 cc of Ondansetron (Caspian Tamin Pharmaceutical, Iran) via the neuraxial route.
Category
Treatment - Drugs

2

Description
Group 2:Patients will receive 75 mg of Bupivacaine (Exir Pharmaceutical, Iran) combined with 10–15 mg of Pethidine (Aburaihan Pharmaceutical, Iran) via the neuraxial route.
Category
Treatment - Drugs

3

Description
Group 3:Patients will receive 75 mg of Bupivacaine (Exir Pharmaceutical, Iran) combined with 10–15 mcg of Dexmedetomidine (Exir Pharmaceutical, Iran) via the neuraxial route.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Valiasr Hospital
Full name of responsible person
Rasoul Jafari
Street address
Hazrat Vali Asr Educational and Medical Center, Hazrat Vali Asr Square, Arak
City
Arak
Province
Markazi
Postal code
3814957558
Phone
+98 86 3222 2003
Email
pr_valieasr@arakmu.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Arak University of Medical Sciences
Full name of responsible person
Rasoul Jafari
Street address
Hazrat Vali Asr Educational and Medical Center, Hazrat Vali Asr Square, Arak
City
Arak
Province
Markazi
Postal code
3814957558
Phone
+98 86 3222 2003
Email
pr_valieasr@arakmu.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Arak 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
Arak University of Medical Sciences
Full name of responsible person
Rasoul Jafari
Position
Assistant Professor
Latest degree
Subspecialist
Other areas of specialty/work
Urology
Street address
Hazrat Valiasr Educational and Medical Center, Hazrat Valiasr Square, Arak
City
Arak
Province
Markazi
Postal code
3814957558
Phone
+98 86 3222 2003
Email
Fateme.akhavan2021@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Arak University of Medical Sciences
Full name of responsible person
Rasoul Jafari
Position
Assistant Professor
Latest degree
Subspecialist
Other areas of specialty/work
Urology
Street address
Hazrat Valiasr Educational and Medical Center, Hazrat Valiasr Square, Arak
City
Arak
Province
Markazi
Postal code
3814957558
Phone
+98 86 3222 2003
Fax
+98 86 3223 1283
Email
fateme.akhavan2021@gmail.com

Person responsible for updating data

Contact
Name of organization / entity
Arak University of Medical Sciences
Full name of responsible person
فاطمه اخوان ملایری
Position
Student
Latest degree
A Level or less
Other areas of specialty/work
Medical Education
Street address
Building 870, Deylami Ave, Azod Ave, Abbas Abbad Ave, Arak
City
Arak
Province
Markazi
Postal code
3813663817
Phone
+98 86 3224 2043
Email
fateme.akhavan2021@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is 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
Undecided - It is not yet known if there will be a plan to make this available
Title and more details about the data/document
Final result
When the data will become available and for how long
A few months after the results were published
To whom data/document is available
Academic and scientific institutions
Under which criteria data/document could be used
Use in proposals and articles
From where data/document is obtainable
Fatemeh Akhavan malayeri
fateme.akhavan2021@gmail.com
What processes are involved for a request to access data/document
fateme.akhavan2021@gmail.com
Comments