Clinical Trial Protocol
Iranian Registry of Clinical Trials

02 Jul 2026

Comparing the effect of Trendelenburg with Supine position on the quality of the surgical field, hemodynamic, cerebral oximetry and cognitive function of patients under open radical prostatectomy procedure

Protocol summary

Study aim

Comparing the effect of Trendelenburg with Supine position on the quality of the surgical field, hemodynamic, cerebral oximetry and cognitive function of patients under open radical prostatectomy procedure

Design

Clinical trial with control group, parallel group trial, on 60 patients. Block randomization method will be used.

Settings and conduct

Subjects will allocate to two equal groups of Trendelenburg and Supine position using block randomization method. After induction of general anesthesia, subjects will be placed in a Trendelenburg or supine position. Completion of tools will be done before and after the positioning at several times. This study will done in Shahid Beheshti hospital of Hamadan university of medical sciences.

Participants/Inclusion and exclusion criteria

Tendency to participate in the study, Indication for open prostatectomy surgery, Having ASA Physical Status I or II, No history of ischemic injuries or cerebrovascular hemorrhage, No history of degenerative neurological diseases (such as Alzheimer and Parkinson) and any intracranial pathology

Intervention groups

Subjects in Trendelenburg position group will be placed in 15° Trendelenburg by tilting the operating table before starting surgery. Supine position group: Subjects in supine position group will be stay in sleeping position on the back during surgery.

Main outcome variables

Quality of the surgical field, Hemodynamic, Cerebral oximetry, Cognitive function

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220410054482N1**
Registration date: **2022-06-01, 1401/03/11**
Registration timing: **retrospective**

Last update: **2022-06-01, 1401/03/11**
Update count: **0**

Registration date

2022-06-01, 1401/03/11

Registrant information

Name

Hanieh Bahadori

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-04-09, 1401/01/20

Expected recruitment end date

2022-05-10, 1401/02/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Comparing the effect of Trendelenburg with Supine position on the quality of the surgical field, hemodynamic, cerebral oximetry and cognitive function of patients under open radical prostatectomy procedure

Public title
Comparing the effect of Trendelenburg with Supine position on the quality of the surgical field, hemodynamic, cerebral oximetry and cognitive function of patients under open radical prostatectomy procedure

Purpose
Prevention

Inclusion/Exclusion criteria

Inclusion criteria:
Tendency to participate in the study Indication for open radical prostatectomy surgery Having ASA Physical Status I or II

Exclusion criteria:
History of ischemic injuries or cerebrovascular hemorrhage History of degenerative neurological diseases (such as Alzheimer and Parkinson) and any intracranial pathology

Age
No age limit

Gender
Male

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
Subjects (60 patients) will allocate to two equal groups (each group 30 patients) of intervention (A) and control (B) using blocking randomization method. Randomization tool is the random allocation software version 1. The software and instructions for using it are available at https://mahmoodsaghaei.tripod.com/Softwares/randalloc.html. After installing the program, to generate a random sequence, the number of groups (2 groups), the name of each group (A= 1, B= 2), the sample size (60 patients) and the block size (number 4) will be entered into the software. Accordingly, 15 blocks of 4, including two groups A and B, will be randomly designed by the software. To conceal, we use Allocation concealment, which refers to the method used to perform a random sequence on study participants, so that the assigned group is not identified before the individual is assigned. Using non-transparent envelopes sealed with random sequences (Sequentially numbered, sealed, opaque envelopes). They are placed in order. In order to maintain the random sequence, numbering is done on the outer surface of the envelopes in the same way. Finally, the lids of the letter envelopes are glued and placed inside a box, respectively. At the beginning of the registration of participants, based on the order of entry of eligible participants in the study, one of the envelopes of the letter will be opened in order and the assigned group of the participant will be revealed.

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Research Ethics Committee of Hamadan University of Medical Sciences

Street address
Vice-chancellor for Research the Technology, Hamadan University of Medical Sciences, Shahid Fahmideh Ave

City
Hamadan

Province
Hamadan

Postal code
6517838695

Approval date
2022-04-09, 1401/01/20

Ethics committee reference number
IR.UMSHA.REC.1401.033

Health conditions studied

1

Description of health condition studied
Open radical prostatectomy

ICD-10 code
N40

ICD-10 code description
Enlarged prostate

Primary outcomes

1

Description
Quality of the surgical field

Timepoint
After surgery

Method of measurement
Criteria for evaluating the quality of the surgical field

2

Description
Hemodynamic
Timepoint
Before anesthesia, after induction of anesthesia, after positioning, every 10 minutes after the start of surgery and at the end of surgery
Method of measurement
Heart rate and non-invasive blood pressure monitoring device

3

Description
Cerebral oximetry
Timepoint
Before anesthesia, after induction of anesthesia, after positioning, every 10 minutes after the start of surgery and at the end of surgery
Method of measurement
Near-Infrared Spectroscopy device

4

Description
Cognitive function
Timepoint
Before and 6 hours after surgery
Method of measurement
Mini-mental state examination

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Subjects will be placed in 15° Trendelenburg by tilting the operating table before starting surgery.
Category
Prevention

2

Description
Control group: Subjects will be stay in sleeping position on the back during surgery.
Category
Prevention

Recruitment centers

1

Recruitment center
Name of recruitment center
Shahid Beheshti Hospital
Full name of responsible person
Dr Seyed Mahdi Hosseini
Street address
Shahid Beheshti Hospital, Eram Ave.
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Hamedan University of Medical Sciences
Full name of responsible person
Dr Reza Shokuhi
Street address
Vice-chancellor for Research the Technology, Hamadan University of Medical Sciences, Shahid Fahmideh Ave
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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
Hamedan 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
Hamedan University of Medical Sciences
Full name of responsible person

Hanieh Bahadori

Position
MSc Student

Latest degree
Bachelor

Other areas of specialty/work
Others

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