

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

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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

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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