Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Assessment of Vital Signs alterations in Classic Spinal versus General Anesthesia methods in inguinal herniorrhaphy

Protocol summary

Study aim

1- Determination of vital Signs changes in classical Spinal procedures and general anesthesia in inguinal hernia surgery 2- Determining the rate of vital Signs changes in classical spinal procedures and general anesthesia in inguinal hernia Surgery based on age 3- Determining the rate of vital signs changes in classical spinal procedures and general anesthesia in inguinal hernia surgery based on gender 4- Determination of vital signs changes in classical spinal procedures and general anesthesia in inguinal hernia surgery based on BMI 5- Determination of vital signs changes in classical spinal procedures and general anesthesia in inguinal hernia surgery based on duration of surgery

Design

Clinical efficiency that randomly select 120 patients and the study is factorial and unilateral blind and analyzed by SPSS software version 25.

Settings and conduct

In this study, 120 patients referred to the hospital (for inguinal hernia surgery by classical spinal procedure or general anesthesia) will be selected and checked that only the participants are blind (unilateral blind) i.e. they have no knowledge of how to perform the study and the changes of vital signs in recovery and every 30 minutes up to two hours after surgery are measured and compared before surgery.

Participants/Inclusion and exclusion criteria

Inclusion criteria are CLASS 1 and 2 ASA and electrical and BMI between 20 and 30. Exclusion criteria include ICP rise, coagulation disorders, local skin infection, preoperative low pressures, anxiety and unwillingness to participate in the study

Intervention groups

patients in the first intervention group will be patients who have inguinal hernia and will undergo classical spinal anesthesia and the second group will be patients who have inguinal hernia and will undergo general anesthesia

Main outcome variables

Vital Signs (RR, PR, T, BP)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20211110053034N1**
Registration date: **2021-12-22, 1400/10/01**
Registration timing: **prospective**

Last update: **2021-12-22, 1400/10/01**
Update count: **0**

Registration date

2021-12-22, 1400/10/01

Registrant information

Name
Mahbobeh Bayat
Name of organization / entity
Country
Iran (Islamic Republic of)
Phone
+98 21 3375 7078
Email address
aydabayat136@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-03-07, 1400/12/16

Expected recruitment end date

2022-09-07, 1401/06/16

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Assessment of Vital Signs alterations in Classic Spinal versus General Anesthesia methods in inguinal herniorrhaphy

Public title
General evaluation of the Patient in two Models of lumbar Anesthesia and general Anesthesia in hernia Wind Surgery

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
CLASS 1 and 2 ASA Elective BMI between 20 and 30
Exclusion criteria:
ICP rise Coagulation Disorders Local skin Infection Preoperative low Pressures Anxiety and Unwillingness to participate in the Study

Age
From **19 years** old to **70 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Participant

Sample size
Target sample size: **120**

Randomization (investigator's opinion)
N/A

Randomization description

Blinding (investigator's opinion)
Single blinded

Blinding description
All participants in the study, who have entry criteria and exit criteria, will not know how to do the study because otherwise, stress affects the vital signs, so only the participating group will not know.

Placebo
Not used

Assignment
Factorial

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Islamic Azad University of Shahroud
Street address
No.6, East first sarvestan, Ave Laleha,Square Namaz
City
Shahr-e Rey
Province
Tehran
Postal code
1846684556

Approval date
2021-02-06, 1399/11/18

Ethics committee reference number
IR.IAU.SHAHROOD.REC.1399.079

Health conditions studied

1

Description of health condition studied
hernia

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
The primary outcome variable that has been recorded for 120 people (sample size) is vital signs including BP, PR, T, RR, which by recording changes in vital signs, the effect of two models of anesthesia (classic spinal "60 people" and general anesthesia "60 people") is determined.

Timepoint
In these two groups, changes in vital signs in recovery and every 30 minutes up to 2 hours after surgery are measured and compared with the preoperative phase as well as between the two groups.

Method of measurement
Checklist

Secondary outcomes

empty

Intervention groups

1

Description
There are The two intervention groups that both groups are subjected to inguinal hernia surgery (each group of 60 people)of the first intervention group under the classical spinal anesthesia and the drug used Bupivacaine with the brand name Marcaine is injected in to the epidural space of the spinal canal and normally begins to take effect within 15 minutes and it remains for up to 8 h ours. (marcaine half a percent in form 15 mg/kg)

Category
Treatment - Drugs

2

Description
Intervention group: The second intervention group is subject to general anesthesia (GA)and the drug Nesdonal (Thiopental) is used and normally at a dose of 3 to 5 mg / kg , which causes anesthesia within 30 seconds after injection, and in the end the two groups will be compared in terms of changes of vital signs before and after action

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Khatam al-Nabiya Hospital in Shahroud
Full name of responsible person
Yousef Kolookhi
Street address
No.6,East first sarvestan,Ave Laleha,Square Namaz,
City
Shahr-e Rey
Province
Tehran
Postal code
1846684556
Phone
+98 21 3375 7078
Email
aydabayat136@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahroud University of Medical Sciences
Full name of responsible person
Behrooz Yahyaee
Street address
No.6,East first sarvestan,Ave Laleha, Square Namaz
City
Shahr-e Rey
Province
Tehran
Postal code
1846684556
Phone
+98 21 3375 7078
Email
aydabayat136@gmail.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Shahroud 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
Shahroud University of Medical Sciences
Full name of responsible person
Yousef Kolookhi
Position
Assistant Professor
Latest degree
Specialist
Other areas of specialty/work
Anesthesiology
Street address
No.6,East first sarvestan,Ave Laleha ,Square Namaz
City
Shahr-e Rey
Province
Tehran
Postal code
1846684556
Phone
+98 21 3375 7078
Email
aydabayat136@gmail.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Shahroud University of Medical Sciences
Full name of responsible person
Yousef Kolookhi
Position
Assistant Professor
Latest degree
Specialist
Other areas of specialty/work
Anesthesiology
Street address
No.6,East first sarvestan,Ave Laleha,Square Namaz
City
Shahr-e Rey
Province
Tehran
Postal code
1846684556
Phone
+98 21 3375 7078

Email
aydabayat136@gmail.com

Person responsible for updating data

Contact

Name of organization / entity
Shahroud University of Medical Sciences

Full name of responsible person
Mahbobeh Bayat

Position
Medical student

Latest degree
Medical doctor

Other areas of specialty/work
General Practitioner

Street address
No.6,East first sarvestan,Ave Laleha,Square Namaz

City
Shahr-e Rey

Province
Tehran

Postal code
1846684556

Phone
+98 21 3375 7078

Email
aydabayat136@gmail.com

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