

Clinical Trial Protocol

Iranian Registry of Clinical Trials

22 Jul 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

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

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahroud University of Medical Sciences

Full name of responsible person

Behrooz Yahyaee

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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

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

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Person responsible for scientific inquiries

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Name of organization / entity

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Full name of responsible person

Yousef Kolookhi

Position

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Latest degree

Specialist

Other areas of specialty/work

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Person responsible for updating data**Contact****Name of organization / entity**

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Position

Medical student

Latest degree

Medical doctor

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General Practitioner

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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