

Clinical Trial Protocol

Iranian Registry of Clinical Trials

20 Sep 2026

Evaluation of the effect of vibration in reducing pain and movement of the patient during spinal anesthesia

Protocol summary

Study aim

Determining the effect of vibration in reducing pain and movement of the patient during spinal anesthesia

Design

Clinical trial with control and intervention group, double-blind, randomized, on 68 patients. Excel software rand function was used for randomization.

Settings and conduct

This study will be performed in Imam Khomeini Hospital. Patients who come to the operating room for abdominal surgery or surgery that can be performed with spinal anesthesia are examined and patients are talked to before the operation and the research process will be explained to patients and patients' informed consent will be obtained and they will enter the study. The group that undergoes spinal anesthesia in the usual way and the other group that undergoes spinal anesthesia by vibrator method

Participants/Inclusion and exclusion criteria

Patients who come to the operating room for abdominal surgery or surgeries with spinal anesthesia will be interviewed before the operation and the research process will be fully explained to the volunteers after filling out the informed consent form. And we include people in the study. Inclusion criteria for patients: 1. Patients who are candidates for abdominal surgery including hernioraphy, mesh implantation, gastrostomy and jejunostomy 2. Age group 20 to 70 years 3. ASA are also 1-3 Exclusion criteria: 1. Spinal anesthesia should be abolished and we should have to anesthetize the patient with wax for surgery and our anesthesia should not be enough for surgery. 2. The anesthesia is incomplete and we have to use drugs or ketamine to continue the surgery.

Intervention groups

We randomly divide patients into 2 groups: 1. A group for which we perform non-vibratory spinal anesthesia 2. A group where we intervene and place the vibrator in the place where we want to insert the needle

Main outcome variables

pain

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220107053657N1**

Registration date: **2022-02-22, 1400/12/03**

Registration timing: **retrospective**

Last update: **2022-02-22, 1400/12/03**

Update count: **0**

Registration date

2022-02-22, 1400/12/03

Registrant information

Name

Fatemeh Refahi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2286 1226

Email address

shaqayeqrefahi6@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-02-01, 1400/11/12

Expected recruitment end date

2022-02-21, 1400/12/02

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effect of vibration in reducing pain and movement of the patient during spinal anesthesia

Public title

Evaluation of vibration in pain in spinal anesthesia

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

Candidate patients for abdominal surgery including herniorrhage, mesh implantation section ,gastrostomy and jejunostomy Age group 20 to 70 years They are also ASA 1-3

Exclusion criteria:

Spinal anesthesia should be abolished and we should have to anesthetize the patient with general anesthesia for surgery, and our anesthesia should not be sufficient for surgery. The anesthesia is incomplete and we have to use drugs or ketamine to continue the surgery.

Age

From **20 years** old to **70 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **68**

Randomization (investigator's opinion)

Randomized

Randomization description

The list of random allocation of patients will be available only to the epidemiologist of the project. To hide the random allocation process, the corresponding treatment type will be written on 68 cardboard and will be placed in a paper envelope. Only the design methodologist will be aware of the contents of the envelopes. The cards will be arranged in a randomized list inside the box. Random allocation software is also used for randomization tools. In addition to simple randomization, these random sequence generation software is able to generate random sequences. When the physician declares a patient eligible, the methodologist will provide the therapist with an envelope design. The person assessing the intended outcomes is a third party who is unaware of the random allocation process and the type of treatment performed. To analyze the data, a statistician who is separate from the study process and is unaware of all the processes performed will be used.

Blinding (investigator's opinion)

Double blinded

Blinding description

The patient takes the drug (intervention or comparison group) in sealed envelopes that code Have been received. Coded by one of the design partners And the

doctor and the evaluator and the patient are blind

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Research Ethics Committees of School of Medicine-
Tehran University of Medical Sciences

Street address

Tehran Province, Tehran, Pour Sina St, Iran

City

Tehran

Province

Tehran

Postal code

1417653761

Approval date

2021-05-15, 1400/02/25

Ethics committee reference number

IR.TUMS.MEDICINE.REC.1400.155

Health conditions studied**1****Description of health condition studied**

spinal anesthesia

ICD-10 code

O74.5

ICD-10 code description

Spinal and epidural anesthesia-induced headache during labor and delivery

2**Description of health condition studied**

spinal anesthesia

ICD-10 code

O74.6

ICD-10 code description

Other complications of spinal and epidural anesthesia during labor and delivery

Primary outcomes**1****Description**

pain

Timepoint

after intervention, one week, one month after

intervention
Method of measurement
Visual Analogue Scale

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: vibration on location of spinal anesthesia. To perform spinal anesthesia, we sit the patient and in the middle line in the space between the vertebrae L4 and L5, we sterilize the area where the needle enters and we put the vibrator device in the sterile cover and we put it for 30 seconds to 1 minute and then a little We move and finally continue the vibration at the entrance of the needle and under the supervision of a doctor under constant anesthesia, insert the needle during the study process and then remove the mandrel and after removing the CSF fluid (cerebrospinal fluid) local anesthetic We prescribe 0.5% bupivacaine depending on the surgical site between 10-15 mg and then remove the needle and bandage the site and put the patient to sleep in supine position.

Category

Treatment - Devices

2

Description

Control group: Spinal anesthesia was performed without vibrator. To perform spinal anesthesia, we sit the patient and sterilize the area where the needle is inserted in the middle line in the space between L4 and L5 vertebrae. When CSF (cerebrospinal fluid) is removed, we prescribe a local anesthetic, bupivacaine 0.5%, depending on the surgical site, between 15 and 15 mg, and then remove the needle, bandage the area, and put the patient to sleep in a supine position.

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

Amiralam hospital

Full name of responsible person

Nader Ali Nazemian Yazdi

Street address

Tehran, Enghelab St. (Darvazeh Dolat), the beginning of Saadi St.

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hamiralam@sina.tums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Dr. Akbar Fotouhi

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Tehran, Enghelab St. (Darvazeh Dolat), the beginning of Saadi St.

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Grant name

Vice Chancellor for Research, Tehran University of Medical Sciences

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Tehran 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

Tehran University of Medical Sciences

Full name of responsible person

Nader Ali Nazemian Yazdi

Position

Assistant Professor of Anesthesiology

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

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Position

Assistant Professor of Anesthesiology

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Specialist

Other areas of specialty/work

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Person responsible for updating data

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Name of organization / entity

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Position

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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