

Clinical Trial Protocol

Iranian Registry of Clinical Trials

07 Jun 2026

incidence of low back pain after spinal anesthesia by Madin and Paramedin methods in non-pregnant women undergoing short-term surgery

Protocol summary

Study aim

Comparison of the incidence of low back pain after spinal anesthesia by Madin and Paramedin methods in non-pregnant women undergoing short-term surgery in Bouali Hospital in 1399-1400

Design

Two-group, double-blind, randomized, on 106 patients

Settings and conduct

This study is performed on 106 non-pregnant women referred to Bu Ali Hospital in the years 1300-1400 who are candidates for short-term surgery. 53 of them undergo median method and 53 patients undergo paramedin method under spinal anesthesia. After surgery and recovery in four stages (after recovery and after transfer to the ward every 6 hours) for low back pain They are evaluated. After discharge, the patient is examined for back pain for 4 weeks and once a week during a telephone call. This evaluation is done through Visual Analog Scale. Then the amount of pain for each person in the questionnaire Relevant is registered.

Participants/Inclusion and exclusion criteria

Obtaining informed consent; Women 18 to 68 years old; ASA Class 1 and 2; No history of spinal surgery; - No contraindication to SA; No history of back pain and headache in previous SAs; No history of any previous severe non-traumatic low back pain; No serious trauma to the spine; Lack of emergency surgery

Intervention groups

Intervention group 1: undergoing spinal anesthesia by median method. Intervention group 2: undergoing paramedin

Main outcome variables

Intensity back pain

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210930052642N1**

Registration date: **2021-10-27, 1400/08/05**

Registration timing: **registered_while_recruiting**

Last update: **2021-10-27, 1400/08/05**

Update count: **0**

Registration date

2021-10-27, 1400/08/05

Registrant information

Name

ali shafiei

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 7774 2599

Email address

alish9574@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-10-08, 1400/07/16

Expected recruitment end date

2021-12-29, 1400/10/08

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

incidence of low back pain after spinal anesthesia by

Madin and Paramedin methods in non-pregnant women undergoing short-term surgery

Public title

incidence of low back pain after spinal anesthesia by Madin and Paramedin methods in non-pregnant women undergoing short-term surgery

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Obtaining informed consent Women 18 to 68 years old ASA Class 1 and 2

Exclusion criteria:

Age

From **18 years** old to **68 years** old

Gender

Female

Phase

N/A

Groups that have been masked

- Participant
- Care provider

Sample size

Target sample size: **106**

Randomization (investigator's opinion)

Randomized

Randomization description

Simple individual randomization: A simple random method will be divided into intervention or control. The tool used will be a random number table. By selecting a number at random and specifying the direction of movement, people will be assigned to the control group if it shows the direction of movement of an even number. If it shows an odd number of people will be given to the intervention group. The output is that people are randomly divided into two equal groups.

Blinding (investigator's opinion)

Double blinded

Blinding description

Participants: Participants in this study were unaware of the type of spinal sensation performed. Clinical caregivers: The doctors who performed the project did not know that low back pain would be studied in patients undergoing spinal anesthesia.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Tehran Azad University of Medical Sciences

Street address

Tehranpars - Farjam St. - Shahid Tanhajoo Alley - No. 106- Unit1

City

Tehran

Province

Tehran

Postal code

1653944383

Approval date

2020-01-18, 1398/10/28

Ethics committee reference number

IR.IAU.TMU.REC.1399.471

Health conditions studied

1

Description of health condition studied

back ache

ICD-10 code

M54.5

ICD-10 code description

Low back pain

Primary outcomes

1

Description

Low back pain intensity score in the questionnaire

Timepoint

Measurement of low back pain after surgery 6, 12 and 18 hours after surgery and 7, 14, 21 and 28 days after surgery

Method of measurement

Back pain severity questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

First intervention group: Prevalence of low back pain in Median method.

Category

Treatment - Surgery

2

Description

The second intervention group: the prevalence of low back pain in the paramedian method

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Bo Ali Hospital

Full name of responsible person

Kourosh Farazmehr

Street address

Imam Hossein Square - Damavand Street - Next to Imam Ali Highway - Bouali Hospital

City

Tehran

Province

Tehran

Postal code

1653944383

Phone

+98 21 7706 7702

Email

alish9574@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Islamic Azad University

Full name of responsible person

Kourosh Farazmehr

Street address

Tehranpars - Farjam St. - Shahid Tanhajoo Alley - No. 106 - Unit1

City

Tehran

Province

Tehran

Postal code

1653944383

Phone

+98 21 7706 7702

Email

alish9574@gmail.com

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Islamic Azad University

Proportion provided by this source

100

Public or private sector

Private

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

Islamic Azad University

Full name of responsible person

Kourosh Farazmehr

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

Street address

Tehranpars, Parvin Square, Shahid Goodarzi Alley - No. 11 - Unit 4

City

Tehran

Province

Tehran

Postal code

1653944383

Phone

+98 21 7774 2599

Email

alish9574@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Islamic Azad University

Full name of responsible person

Kourosh Farazmehr

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

Street address

Tehranpars, Parvin Square, Shahid Goodarzi Alley - No. 11 - Unit 4

City

Tehran

Province

Tehran

Postal code

1653944383

Phone

+98 21 7706 7702

Email

alish95@gmail.com

Person responsible for updating data

Contact

Name of organization / entity

Islamic Azad University

Full name of responsible person

Kourosh Farazmehr

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

Street address

Tehranpars, Parvin Square, Shahid Goodarzi Alley -
No. 11 - Unit 4

City

Tehran

Province

Tehran

Postal code

1653944383

Phone

+98 21 7774 2599

Email

alish9574@gmail.com

Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available

Title and more details about the data/document

All data is potentially shareable after unidentified individuals

When the data will become available and for how long

Start of access period 2 years after printing results

To whom data/document is available

Everyone

Under which criteria data/document could be used

There are no special conditions

From where data/document is obtainable

Includes mailing address for correspondence

What processes are involved for a request to access data/document

Use the postal address after request for up to one month

Comments