# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

18 Sep 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**
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**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

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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**
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

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## Person responsible for scientific inquiries

**Contact**

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**Full name of responsible person**
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**Position**
Associate professor

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Specialist

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## Person responsible for updating data

**Contact**

**Name of organization / entity**
Islamic Azad University

**Full name of responsible person**
Kourosh Farazmehr
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Associate professor
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## 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**