

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

comparison of the effect of using ultrasonography with the traditional method on success rate of spinal anesthesia by the resident of anesthesia

Protocol summary

Study aim

Comparison of the effect of using ultrasonography the traditional method on the success rate of spinal anesthesia by the resident of anesthesia

Design

design: clinical trial, randomized, Double-blind, has a control group, parallel, with 60 patients

Settings and conduct

The study will be conducted at Firoozgar and Rasul Akram Hospital, 60 patients were randomized to one another divided into two groups: Landmark and Ultrasound groups, in both groups of patients they are in sitting position, in landmark group spinal anesthesia is performed with the midline approach, in Ultrasound groups before spinal anesthesia ultrasound is selected from the lumbar spine

Participants/Inclusion and exclusion criteria

Inclusion criteria: patients with a BMI of between 24 and 30 who have an informed consent. Exclusion criteria: history of lumbar surgery, spinous process are touched hard or do not touched, patients who have contraindication to spinal anesthesia

Intervention groups

Patients are divided into two groups: spinal anesthesia with ultrasonography and traditional methods.

Main outcome variables

Effect of ultrasonography

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20140109016151N8**

Registration date: **2019-02-22, 1397/12/03**

Registration timing: **registered_while_recruiting**

Last update: **2019-02-22, 1397/12/03**

Update count: **0**

Registration date

2019-02-22, 1397/12/03

Registrant information

Name

Alireza Pournajafian

Name of organization / entity

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Country

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-01-05, 1396/10/15

Expected recruitment end date

2019-08-23, 1398/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

comparison of the effect of using ultrasonography with the traditional method on success rate of spinal anesthesia by the resident of anesthesia

Public title

the effect of ultrasonography on the success rate of spinal anesthesia by the resident of anesthesia

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

patients with a BMI between 24 and 30 who have an informed consent for spinal anesthesia for surgery

Exclusion criteria:

history of lumbar spine surgery patients with a BMI greater than 30 spinose process are touched hard or do not touch patients who do not have an informed consent patients who have contraindications to spinal anesthesia

Age

From **18 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Simple randomization, individual, sealed envelopes, coin flipping

Blinding (investigator's opinion)

Double blinded

Blinding description

patient and principal investigator are unaware of how to perform spinal anesthesia using the traditional or ultrasonographic method before starting

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics committee of Iran University of Medical Sciences

Street address

Fifth floor, Central building, Iran University of Medical Sciences, Hemmat Highway

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1449614535

Approval date

2017-12-25, 1396/10/04

Ethics committee reference number

IR.IUMS.FMD.REC 1396.9511174004

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

Spinal anesthesia by ultrasound

ICD-10 code

U00-U85

ICD-10 code description

Special purposes

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

success in spinal anesthesia

Timepoint

spinal anesthesia during surgery

Method of measurement

based on a visual scale VAS

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: spinal anesthesia with ultrasonography

Category

Other

2**Description**

Control group: Spinal anesthesia with the traditional method

Category

Other

Recruitment centers**1****Recruitment center****Name of recruitment center**

Firuzgar Hospital

Full name of responsible person

Dr. Alireza Pournajafian

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Sponsors / Funding sources

1

Sponsor

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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
Iran 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
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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

all data can be shared after making people unidentifiable

When the data will become available and for how long

Access period from 2021

To whom data/document is available

all people

Under which criteria data/document could be used

it is free for non-commercial use

From where data/document is obtainable

sending Email to: a-pournajafian@tums.ac.ir

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

after receiving the individual and organizational specifications, the applicant will be responded up to one month

Comments