

Clinical Trial Protocol

Iranian Registry of Clinical Trials

20 Jun 2026

Comparison of the effects of two drugs, propofol and isoflurane, as anesthetic agents on gene expression mt-DNA in posterior vertebral fixation surgeries

Protocol summary

Study aim

The aim is to investigate the effect of using two drugs, propofol and isoflurane, as commonly used drugs in anesthesia with anti-inflammatory effects, in reducing the level of mtDNA expression, which plays an important role in regulating inflammatory processes during PSF surgery and can generally determine the prognosis.

Design

A controlled, parallel-group, single-blind, randomized, phase 2 clinical trial on 34 patients. IZE Android software was used for randomization.

Settings and conduct

This study will be conducted in the form of single blind clinical trial (project participants) on patients who are candidates for PSF surgery referring to Shahada Tajrish Hospital in Tehran.

Participants/Inclusion and exclusion criteria

Patients who are candidates for elective surgery for posterior stabilization of the lumbar spine in Shahada Tajrish Hospital will be studied. The exclusion criteria for this study include: Previous history of surgery; ASA class III or higher; Malignancies; Cardiovascular diseases; Chronic inflammatory diseases; Corticosteroid use; Emergency surgery; Any instability of the patient during surgery; Drug addiction.

Intervention groups

Intervention group after induction of anesthesia. Then propofol with a dose of 0.1 to 0.2 mg/kg/min is used to maintain anesthesia in group one and isoflurane 1 to 2.5% is used by inhalation in group two. Patients' blood samples will be measured in order to check the level of mt-DNA expression before surgery, after induction of anesthesia, 24 hours after surgery, and the effect of these two drugs on them will be investigated.

Main outcome variables

The duration of the operation; the amount of bleeding and the complications of the surgery; the amount of

medication used; the level of mt-DNA along with other demographic information of the patients will be recorded in the questionnaires prepared by the study researchers.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190121042444N5**

Registration date: **2024-02-11, 1402/11/22**

Registration timing: **registered_while_recruiting**

Last update: **2024-02-11, 1402/11/22**

Update count: **0**

Registration date

2024-02-11, 1402/11/22

Registrant information

Name

faranak behnaz

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 21 2274 1174

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-12-12, 1402/09/21

Expected recruitment end date

2025-12-12, 1404/09/21

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effects of two drugs, propofol and isoflurane, as anesthetic agents on gene expression mt-DNA in posterior vertebral fixation surgeries

Public title

"Investigation of the effect of anesthetic propofol on gene expression"; "Investigation of the effect of the anesthetic Isoflurane on gene expression"

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Patients who are candidates for elective surgery for posterior stabilization of the lumbar spine ASA class I-II

Exclusion criteria:

Previous history of surgery ASA class III or higher
Malignancies Cardiovascular diseases Chronic inflammatory diseases Corticosteroid use Emergency surgery Any instability of the patient during surgery Drug addiction

Age

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

Gender

Both

Phase

3

Groups that have been masked

- Participant

Sample size

Target sample size: **34**

Randomization (investigator's opinion)

Randomized

Randomization description

The participants in the study are divided into two groups, control and intervention, using a randomizer software, so that at first, each patient is given a number by the researcher, and it is entered into the IZE Android software, and the output of the patient software is as It introduces groups A and B. 34 patients will be included in the study and will be divided into two groups of 17 people.

Blinding (investigator's opinion)

Single blinded

Blinding description

Patients are introduced to the data collector to continue the study so that only the numbers A and B are written on the form in the patient's hand, and as a result, the patient and the data collector are not aware of the patient group.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics committee of Shahid Behesti University of Medical Sciences

Street address

Yaman Ave,Velenjak

City

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Province

Tehran

Postal code

1467664961

Approval date

2023-11-26, 1402/09/05

Ethics committee reference number

IR.SBMU.RETECH.REC.1402.498

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

Lumbar spine injury

ICD-10 code

S30-S39

ICD-10 code description

Injuries to the abdomen, lower back, lumbar spine and pelvis(S30-S39)

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

level of mt-DNA

Timepoint

before the intervention and 1 hour after the operation and 1 day after the operation

Method of measurement

Measurement of serum levels in a blood test

2**Description**

Duration of surgery

Timepoint

Surgery start time - surgery end time

Method of measurement

minutes

3**Description**

Bleeding volume

Timepoint

End of surgery

Method of measurement

milliliter

4**Description**

Complications of surgery

Timepoint

First of surgery- End of surgery

Method of measurement

Filling out the questionnaire

5**Description**

demographic information

Timepoint

The beginning of surgery

Method of measurement

Filling out the questionnaire based on the birth certificate information

Secondary outcomes

empty

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

Intervention group: In order to induce anesthesia in all patients, midazolam 0.01 mg/kg, fentanyl 2 kg/m μ , lidocaine 1.5 mg/kg, propofol 2.5-2 mg/kg, and cis-etraurium 0.2 mg/kg will be administered. Then propofol with a dose of 0.1 to 0.2 mg/kg/min is used to maintain anesthesia in group one and isoflurane 1 to 2.5% is used by inhalation in group two. In addition, in both groups, atracurium and fentanyl were repeated every 45 minutes. Blood samples were taken in order to measure the mentioned variables once before induction (Baseline) and once one hour after anesthesia and 24 hours after the end of surgery. EDTA containing is collected.

Category

Treatment - Drugs

2**Description**

Control group: No intervention will be performed in this group. Standard treatment will be administrated.

Category

N/A

Recruitment centers**1****Recruitment center**

Name of recruitment center
Shohada Tajrish Hospital

Full name of responsible person

Faranak Behnaz

Street address

Shohada Hospital,Tajrish SQ ,Tehran, Iran

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Shahid Beheshti University of Medical Sciences

Full name of responsible person

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Tajrish Square, Shahada Hospital, Research Center

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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

Shahid Beheshti 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**

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Faranak Behnaz

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

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Associate professor

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

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Full name of responsible person

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

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Faranak Behnaz

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

Only part of the data, such as information about the main consequence or the like, can be shared.

When the data will become available and for how long

Start of access period from 1402

To whom data/document is available

Only for researchers in academic and scientific institutions

Under which criteria data/document could be used

Only data analysis is possible

From where data/document is obtainable

Dr. Faranak Behnaz, Address: Tehran, Tajrish Square, Shohada Experience Hospital, Tel: 0098212271174

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

After submitting the application, a maximum of one week will be answered

Comments