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)

Phone

+98 21 2274 1174

Email address

faranak.behnaz@gmail.com

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
Tehran
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/mμ, lidocaine 1.5 mg/kg, propofol 2.5-2 mg/kg, and cis-etracurium 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
City
Tehran
Province
Tehran
Postal code
1985711151
Phone
+98 21 2274 1174
Email
faranak.behnaz@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Terifeh Dashti
Street address
Tajrish Square, Shahada Hospital, Research Center
City
Tehran
Province
Tehran
Postal code
1985711151
Phone
+98 21 2272 0130
Email
vtt.balini.shohada@gmail.com
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
Street address
Shohada Hospital, Tajrish SQ, Tehran , Iran
City
Tehran
Province
Tehran
Postal code
1985711151
Phone
009821227741174
Email
faranak.behnaz@gmail.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Mehrak Erfanian
Position
Rezident
Latest degree
Medical doctor
Other areas of specialty/work
Anesthesiology
Street address
Shohada Hospital,Tajrish SQ
City
Tehran
Province
Tehran
Postal code
1985711151
Phone
009821227741174
Email
mehrak_erfanian@yahoo.com

Person responsible for updating data

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
Street address
Shohada Hospital,Tajrish SQ
City
Tehran
Province
Tehran
Postal code
1985711151
Phone
009821227741174
Email
faranak.behnaz@gmail.com

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