

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jul 2026

Examining the effect of using the drug propofol in anesthesia on the blood fat and bicarbonate ion levels in patients undergoing spinal surgery

Protocol summary

Study aim

Determination of the effect of using propofol in anesthesia on the level of lipid and bicarbonate ion in patients undergoing spinal surgery

Design

This semi-experimental clinical trial will be conducted in a group of 58 people as a comparison before and after the intervention in one group. The study was not blinded and the sampling was non-probable and accessible.

Settings and conduct

This study will be conducted in the operating room of Allameh Bahloul Gonabadi Hospital on candidates for spine surgery under anesthesia with propofol to measure the effect of propofol on blood characteristics of patients during surgery. Before anesthesia, blood samples will be taken from the patients, and then all patients will be under anesthesia with propofol, and 4 hours after anesthesia, blood samples will be taken again. The results obtained from the studied variables in the sample obtained before and after anesthesia will be compared with each other. The patients and the main researcher of the study were not blinded, but blinding will be done by the person analyzing. So that the data of the study is collected in two groups A and B by the researcher and during the analysis, the person analyzing will not know how to allocate the data in the two groups.

Participants/Inclusion and exclusion criteria

Inclusion criteria Age 20 to 70 years ASA class I and II Without underlying liver and blood disease No addiction No overweight Exclusion criteria: Lack of informed consent Occurrence of heart and blood problems before surgery

Intervention groups

The intervention group includes patients who are candidates for spine surgery under propofol anesthesia.

Main outcome variables

blood pH, bicarbonate ion, and lipid levels(LDL, HDL,

triglycerides, cholesterol)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200501047254N3**

Registration date: **2024-03-02, 1402/12/12**

Registration timing: **registered_while_recruiting**

Last update: **2024-03-02, 1402/12/12**

Update count: **0**

Registration date

2024-03-02, 1402/12/12

Registrant information

Name

Fatemeh Pouladkhay

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 5722 3360

Email address

pouladkhay.fatemeh@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-02-20, 1402/12/01

Expected recruitment end date

2025-02-19, 1403/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Examining the effect of using the drug propofol in anesthesia on the blood fat and bicarbonate ion levels in patients undergoing spinal surgery

Public title

Effect of Propofol Drug on Lipid Level and Blood PH

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Informed consent of the patient to participate in the research Patient age between 20 and 70 years Patient with ASA class I and II Duration of surgery at least 4 hours Blood fat before the operation should be at a normal level (less than 200). Blood pH should be at a normal level before the operation. Do not have underlying diseases including liver and blood diseases. The patient should not be a candidate for surgery due to trauma and in emergency conditions. The patient does not have a history of drug addiction. The patient should not be overweight or obese. The patient does not have a history of taking antipsychotic drugs

Exclusion criteria:

Patient withdrawal from participating in research Occurrence of heart and respiratory problems before the start of the plan

Age

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

Gender

Both

Phase

2-3

Groups that have been masked

- Data analyser

Sample size

Target sample size: **58**

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Blinding is done in one blind way so that the study data is collected in two groups A and B by the researcher and during the analysis, the person analyzing will not know how the data is allocated in the two groups.

Placebo

Not used

Assignment

Other

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Gonabad University of Medical Sciences

Street address

Ghadir Square, Imam Khomeini Street, Gonabad Medical Sciences Headquarters

City

Gonabad

Province

Razavi Khorasan

Postal code

9691793718

Approval date

2024-02-07, 1402/11/18

Ethics committee reference number

lr.gmu.rec.1402.152

Health conditions studied

1

Description of health condition studied

Spine surgery

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Blood triglyceride levels

Timepoint

Before starting NPO, 4 hours after surgery

Method of measurement

Triglyceride test product of Dialab company

Secondary outcomes

1

Description

Blood PH level

Timepoint

Before starting fasting, 4 hours after surgery

Method of measurement

ABG Test

2

Description

Blood bicarbonate ion level

Timepoint

Before starting fasting, 4 hours after surgery

Method of measurement

ABG Test

3

Description

HDL Level

Timepoint

Before starting NPO, 4 hours after surgery

Method of measurement

HDL test product of Dialab company

4

Description

LDL Level

Timepoint

Before starting NPO, 4 hours after surgery

Method of measurement

LDL test product of Bionic company

5

Description

Cholesterol Level

Timepoint

Before starting NPO, 4 hours after surgery

Method of measurement

Cholesterol test product of Dialab company

Intervention groups

1

Description

Intervention group: This group will include patients who are candidates for spine surgery under anesthesia with propofol at a dose of 10 mg/kg/hour Product of B-Broun, Germany that they have been under anesthesia with propofol for at least 4 hours.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center**Name of recruitment center**

Allameh Bahloul Gonabadi Hospital

Full name of responsible person

Mohammad Taghi Khodadadi

Street address

Nurse Blvd., Saadi St., Allameh Bahloul Gonabadi Hospital

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Sponsors / Funding sources

1

Sponsor**Name of organization / entity**

Gonabad University of Medical Sciences

Full name of responsible person

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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

Gonabad 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**

Gonabad University of Medical Sciences

Full name of responsible person

Mohammad Taghi Khodadadi

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

Mohammad Taghi Khodadadi

Position

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Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

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Person responsible for updating data

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Mazandaran University of Medical Sciences

Full name of responsible person

Fatemeh Pouladkhay

Position

Faculty member instructor

Latest degree

Master

Other areas of specialty/work

operation room

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Not applicable

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

When the data will become available and for how long

To whom data/document is available

Under which criteria data/document could be used

From where data/document is obtainable

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

Comments