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)

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+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
Ir.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
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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

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Position
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Other areas of specialty/work
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Person responsible for updating data

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Position
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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
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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