Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Jul 2026

Comparison of changes in Neutrophil-to-Lymphocyte Ratio (NLR) in patients with nausea vomiting and patients without nausea vomiting after spinal anesthesia

Protocol summary

Study aim
Comparison of changes in neutrophil to lymphocyte ratio in patients with nausea and vomiting and patients without nausea and vomiting

Design
The clinical trial, three blind, without randomization on 80 patients

Settings and conduct
This is a three-blind clinical trial that will be conducted on 80 candidates for spinal anesthesia at Kashani Hospital in Isfahan. After the approval of the ethics committee of the university and obtaining the consent of the patients, the patients are subjected to spinal anesthesia and blood samples are taken before and after the spinal and after the end of the operation. Also, the fourth sample, if the patient has nausea and vomiting, immediately after nausea or vomiting. And otherwise, it will be taken from recovery during discharge. The samples are collected in identical and coded tubes and sent to the laboratory immediately. Clinical symptoms of the patient are monitored and recorded from the moment of entering the operating room until the moment of leaving the recovery room. Laboratory experts and people who collect and analyze data do not know about the patient group and are blind.

Participants/Inclusion and exclusion criteria
Inclusion criteria: age 18 to 65, ASA anesthesia class I and II, candidate for spinal anesthesia Non-entry criteria: obesity, cardiovascular and hemodynamic diseases, drug and psychotropic addiction, pregnancy, and breastfeeding.

Intervention groups
In this study, 80 eligible patients were included in the study, and their condition was checked in terms of having or not having nausea and vomiting.

Main outcome variables
Neutrophil to lymphocyte ratio

General information

Reason for update

Acronym
NLR

IRCT registration information
IRCT registration number: **IRCT20160307026950N42**
Registration date: **2022-07-13, 1401/04/22**
Registration timing: **prospective**

Last update: **2022-07-13, 1401/04/22**
Update count: **0**

Registration date
2022-07-13, 1401/04/22

Registrant information

Name
Behzad Nazemroaya

Name of organization / entity
Isfahan University of Medical Sciences

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-07-23, 1401/05/01

Expected recruitment end date
2022-09-23, 1401/07/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison of changes in Neutrophil-to-Lymphocyte Ratio (NLR) in patients with nausea vomiting and patients without nausea vomiting after spinal anesthesia

Public title
Comparison of changes in Neutrophil-to-Lymphocyte Ratio (NLR) in patients with nausea vomiting and patients without nausea vomiting

Purpose
Diagnostic

Inclusion/Exclusion criteria

Inclusion criteria:
Patients 18 to 60 years old Anesthesia class I and II according to ASA criteria Candidate for surgery under spinal anesthesia Informed consent to enter the study

Exclusion criteria:
BMI (Body Mass Index)>30 Cardiovascular diseases and hemodynamic disorders Use of psychotropic or sedative drugs Addiction to opioid and non-opioid drugs Pregnancy and breastfeeding Having diabetes, orthostatic hypotension, bradycardia, hypokalemia, hypothyroidism, depression, long QT syndrome

Age
From **18 years** old to **65 years** old

Gender
Both

Phase
2

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size
Target sample size: **80**

Randomization (investigator's opinion)
N/A

Randomization description

Blinding (investigator's opinion)
Triple blinded

Blinding description
This is a three-way blind clinical trial so that before obtaining consent, the patients are included in the study, but the patient does not know which people are included in the study, and it is assumed that the conditions are the same for everyone, the samples are also inside the tube. Identical forms that only have the characteristics and code of the patient group are placed so that the laboratory experts are also kept blind, those responsible for collecting data, and those who evaluate the outcome also do not know about the patient group are blind.

Placebo
Not used

Assignment
Single

Other design features
In this study, 80 patients are considered and examined to determine how many patients have nausea and vomiting during the study.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee in Biomedical Research, Isfahan University of Medical Sciences

Street address
Hezar Jarib St

City
Isfahan

Province
Isfehan

Postal code
8174673461

Approval date
2022-06-15, 1401/03/25

Ethics committee reference number
IR.MUI.MED.REC.1401.126

Health conditions studied

1

Description of health condition studied
Nausea and vomiting

ICD-10 code
R11

ICD-10 code description
Nausea and vomiting

Primary outcomes

1

Description
Neutrophil to lymphocyte ratio

Timepoint
Before spinal, 20 minutes after spinal, when entering recovery, immediately after nausea and vomiting and when discharged from recovery

Method of measurement
Venous blood sample

Secondary outcomes

1

Description
Blood Pressure

Timepoint
Every 10 minutes from the moment of entering the operating room until the moment of discharge from the recovery

Method of measurement
Sphygmomanometer

2

Description
Heart Rate
Timepoint
From the moment of entering the operating room until the moment of discharge from the recovery
Method of measurement
Electrocardiogram

3

Description
Oxygen saturation
Timepoint
From the moment of entering the operating room until the moment of discharge from the recovery
Method of measurement
Pulse Oximeter

Intervention groups

1

Description
Intervention group: In this study, all 80 eligible patients are monitored after spinal surgery and their symptoms are recorded. Also, before and after spinal surgery and when entering recovery, cbc blood samples are taken from the patient to measure the Neutrophil to Lymphocyte Ratio. Then, in recovery, they are checked for nausea and vomiting, and if they had nausea and vomiting, the fourth sample is taken immediately after, otherwise, when they are discharged from recovery.
Category
Diagnosis

Recruitment centers

1

Recruitment center
Name of recruitment center
Kashani Hospital
Full name of responsible person
Behzad Nazemoroaya
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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
Esfahan 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
Esfahan University of Medical Sciences
Full name of responsible person
Mahmud Falamarz Fuladi
Position
Anesthesiology resident
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Person responsible for scientific inquiries

Contact

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Position

Professor assistant of Anesthesia and Intensive carentensive care

Latest degree

Specialist

Other areas of specialty/work

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Person responsible for updating data

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Position

Nurse Anesthetist

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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

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

Informed Consent Form

Undecided - It is not yet known if there will be 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

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

Data Dictionary

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