

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 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

Country

Iran (Islamic Republic of)

Phone

+98 31 3212 3543

Email address

behzad_nazem@med.mui.ac.ir

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

Isfahan

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

Street address

Kashani St

City

Isfahan

Province

Isfahan

Postal code

8183983434

Phone

+98 31 3233 0091

Email

behzad_nazem@med.mui.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Shaghayegh Haghjoo

Street address

Hezar Jarib

City

Isfahan

Province

Isfahan

Postal code

8174673461

Phone

+98 31 3668 0048

Email

research@mui.ac.ir

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

Latest degree

Medical doctor

Other areas of specialty/work

Anesthesiology

Street address

Hezar Jarib

City

Isfahan

Province

Isfahan

Postal code

8146713543

Phone

+98 31 3620 2020

Email

Leylarafiei943@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Behzad Nazem roaya

Position

Professor assistant of Anesthesia and Intensive care intensive care

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

Street address

Hezar Jarib

City

Isfahan

Province

Isfahan

Postal code

8146713543

Phone

+98 31 3620 2020

Email

behzad_nazem@med.mui.ac.ir

Person responsible for updating data

Contact

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Leyla Rafiei

Position

Nurse Anesthetist

Latest degree

Bachelor

Other areas of specialty/work

Anesthesiology

Street address

Hezar Jarib

City

Isfahan

Province

Isfahan

Postal code

8146713543

Phone

+98 31 3620 2020

Email

Leylarafiei943@gmail.com

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