

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 May 2026

Comparison of hemodynamic responses of Pergabaline and fentanyl after endotracheal intubation in lumbar spine surgery : A double-blind clinical trial

Protocol summary

Study aim

Comparison of hemodynamic responses of Pergabaline and fentanyl after endotracheal intubation in lumbar spine surgery

Design

A randomized, double-blind, three-phase, randomized clinical trial performed on 64 patients at random.

Settings and conduct

The population of this study was aged 20-65 years old who referred to Ayatollah Rouhani Hospital in Babol. Patients are randomly divided into two groups with a table of random numbers by computer. Intervention group: 8 hours before surgery, 75 mg capsules containing pregabalin (Sanamod company) are administered orally. In addition, fentanyl (Caspian company) 1 microgram/kg in 50 ml of normal saline will be given 10 minutes before endotracheal intubation. Control group: Capsules containing placebo are given orally 8 hours before surgery. In addition, fentanyl (Caspian company) 1 microgram/kg in 50 ml of normal saline will be given 10 minutes before endotracheal intubation.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age 20-65 years old; The American Society of Anesthesiologists (ASA) class I&II (Grade 1: No cardiovascular, respiratory, glandular and Grade 2: Controlled diabetes) Exclusion criteria: Drug addiction; hypertension and antihypertensive drugs consumers; Difficult intubation; Bradycardia

Intervention groups

Intervention group: 8 hours before surgery, 75 mg capsules containing pregabalin (Sanamod company) are administered orally. In addition, fentanyl (Caspian company) 1 microgram/kg in 50 ml of normal saline will be given 10 minutes before endotracheal intubation. Control group: Capsules containing placebo are given orally 8 hours before surgery. In addition, fentanyl

(Caspian company) 1 microgram/kg in 50 ml of normal saline will be given 10 minutes before endotracheal intubation.

Main outcome variables

Heart rate; hypertension; pain; intubation quality; arterial blood oxygen

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20111010007752N12**

Registration date: **2021-08-22, 1400/05/31**

Registration timing: **prospective**

Last update: **2021-08-22, 1400/05/31**

Update count: **0**

Registration date

2021-08-22, 1400/05/31

Registrant information

Name

Parviz Amri Maleh

Name of organization / entity

Babol University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 11 1223 8296

Email address

pamrimaleh@mubabol.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-08-23, 1400/06/01

Expected recruitment end date

2022-08-23, 1401/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of hemodynamic responses of Pergabaline and fentanyl after endotracheal intubation in lumbar spine surgery : A double-blind clinical trial

Public title

Comparison of pregabalin and fentanyl after endotracheal intubation

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Age 20-65 years old The American Society of Anesthesiologists (ASA) class I&II (Grade 1: No cardiovascular, respiratory, glandular and Grade 2: Controlled diabetes)

Exclusion criteria:

Drug addiction Hypertension and antihypertensive drugs consumers Difficult intubation Bradycardia

Age

From **20 years** old to **65 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **64**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients will be randomly assigned to two groups of 32 using 4 blocks and a ratio of 1: 1. The free website www.randomization.com will be used to generate the allocation sequence. The resulting sequence will be written on separate sheets and placed in sealed envelopes and will be provided to the lead researcher for study.

Blinding (investigator's opinion)

Double blinded

Blinding description

Pregabalin is in the form of capsules. In order to blind the capsules containing placebo, they are selected in a completely identical shape and identical to pregabalin capsules, so that they are completely similar in terms of smell, color and form. Capsules containing pregabalin and placebo are placed in one-size, one-size-fits-all cans and then a 3-digit code is written on each can. After the patient enters the study, one of these cans is assigned to the patient and the code is written on the can on the

patient's file (study checklist). Unlock the codes will be done after the study.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics Committee of Babol University of Medical Sciences

Street address

Daneshgah Square, Ganjafrooz Avenue

City

Babol

Province

Mazandaran

Postal code

4717647745

Approval date

2021-05-31, 1400/03/10

Ethics committee reference number

IR.MUBABOL.REC.1400.128

Health conditions studied**1****Description of health condition studied**

Acute pain

ICD-10 code

G89.18

ICD-10 code description

Other acute postprocedural pain

Primary outcomes**1****Description**

Blood Pressure

Timepoint

Before prescribing the drug; before laryngoscopy; after intubation, 1, 3, 5,10 minutes after intubation: after surgical incision

Method of measurement

Monitoring of blood pressure, mm Hg

Secondary outcomes

1

Description

Heart Rate

Timepoint

Before prescribing the drug; before laryngoscopy; after intubation, 1, 3, 5,10 minutes after intubation: after surgical incision

Method of measurement

Number per minute

2

Description

O2 saturation

Timepoint

Before prescribing the drug; before laryngoscopy; after intubation, 1, 3, 5,10 minutes after intubation: after surgical incision

Method of measurement

Pulse oximeter

Intervention groups

1

Description

Intervention group: 8 hours before surgery, 75 mg capsules containing pregabalin (Sanamod company) are administered orally. In addition, fentanyl (Caspian company) 1 microgram/kg in 50 ml of normal saline will be given 10 minutes before endotracheal intubation

Category

Treatment - Drugs

2

Description

Control group: Capsules containing placebo are given orally 8 hours before surgery. In addition, fentanyl (Caspian company) 1 microgram/kg in 50 ml of normal saline will be given 10 minutes before endotracheal intubation.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Ayatollah Rouhani Hospital

Full name of responsible person

Parviz Amri

Street address

Ruhani Hospital, Daneshgah Square, Ganjafrooz Avenue

City

Babol

Province

Mazandaran

Postal code

47176-41367

Phone

+98 11 3233 8301

Email

pamrimaleh@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Babol University of Medical Sciences

Full name of responsible person

Reza Ghadimi

Street address

Vice-chancellor Of Research, Daneshgah Square, Ganjafrooz Avenue

City

Babol

Province

Mazandaran

Postal code

47176-41367

Phone

+98 11 3219 7667

Email

rezaghadimi@yahoo.com

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Babol 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

Babol University of Medical Sciences

Full name of responsible person

Parviz Amri

Position

Associated professor

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

Street address

Ayatollah Rouhani Hospital, Daneshgah Square,

Ganjafrooz Avenue

City

Babol

Province

Mazandaran

Postal code

47176-41367

Phone

+98 11 3233 8301

Email

pamrimaleh@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Babol University of Medical Sciences

Full name of responsible person

Parviz amri

Position

Associated Professor

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

Street address

Ayatollah Rouhani Hospital, Daneshgah Square,
Ganjafrooz Avenue

City

Babol

Province

Mazandaran

Postal code

47176-41367

Phone

+98 11 3233 8301

Email

pamrimaleh@gmail.com

Person responsible for updating data

Contact

Name of organization / entity

Babol University of Medical Sciences

Full name of responsible person

parviz Amri

Position

Associated Professor

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

Street address

Ayatollah Rouhani Hospital, Daneshgah Square,
Ganjafrooz Avenue

City

Babol

Province

Mazandaran

Postal code

47176-41367

Phone

+98 11 3233 8301

Email

pamrimaheh@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

There is still no plan for its publish.

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available