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

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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 Siences
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
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Babol University of Medical Sciences
Full name of responsible person
Reza Ghadimi
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Vice-chancellor Of Research, Daneshgah Square, Ganjafrooz Avenue
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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
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Latest degree
Specialist

Other areas of specialty/work
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Person responsible for updating data

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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