Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Comparison of the hemodynamic response of Dexmedetomidine and Fentanyl after tracheal intubation in lumbar spine surgery: Double blind clinical trial

Protocol summary

Study aim
Comparison of the hemodynamic response of Dexmedetomidine and fentanyl after tracheal intubation in lumbar spine surgery: Double blind clinical trial

Design
A randomized clinical trial, with parallel groups, phase 3, without blindness that, 80 patients randomly divided into two groups of 40 subjects with block sizes of 4 and 6.

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 compute. Intervention group: Dexmedetomidine (Imagen Pharmacy) 0.5 mcg/kg in 50 ml of normal saline within 10 minutes before intubation. Control group: Fentanyl (Caspian Company) 1mcg/kg in 50 ml of normal saline within 10 minutes before intubation.

Participants/Inclusion and exclusion criteria
inclusion Criteria: age 20-65 years; ASA class 1-3. Exclusion criteria: drug addiction; hypertension and anti hypertensive drugs consumers; difficult intubation bradycardia.

Intervention groups
Intervention group: Dexmedetomidine (Imagen Pharmacy) 0.5 mcg/kg in 50 ml of normal saline within 10 minutes before intubation. Control group: Fentanyl (Caspian Company) 1mcg/kg in 50 ml of normal saline within 10 minutes before intubation.

Main outcome variables
Heart rate; blood pressure; pain;intubation quality; arterial blood oxygen

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20111010007752N11**
Registration date: **2020-06-27, 1399/04/07**
Registration timing: **retrospective**

Last update: **2020-06-27, 1399/04/07**
Update count: **0**

Registration date
2020-06-27, 1399/04/07

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
2018-12-31, 1397/10/10

Expected recruitment end date
2019-12-31, 1398/10/10

Actual recruitment start date
2018-12-31, 1397/10/10

Actual recruitment end date
2019-12-31, 1398/10/10

Trial completion date
2020-01-01, 1398/10/11

Scientific title
Comparison of the hemodynamic response of

Dexmedetomidine and Fentanyl after tracheal intubation in lumbar spine surgery: Double blind clinical trial

Public title
Comparison of Dexmedetomidine and Fentanyl after tracheal intubation in lumbar spine surgery
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Age 20-65 years old ASA class I&II
Exclusion criteria:
Drug addiction Hypertention and antihypertensive drugs consumers Difficult intubation Bradycardia
Age
From **20 years** old to **65 years** old
Gender
Both

Phase
3
Groups that have been masked
No information
Sample size
Target sample size: **80**
Actual sample size reached: **80**
Randomization (investigator's opinion)
Randomized
Randomization description
Random assignment of the patients into two intervention groups. Patients are randomly divided into two groups A and B with a table of random numbers (a random number table is a collection of numbers that are generated without a specific pattern or order and completely randomized, then samples are randomly selected by Randomizer software.
Blinding (investigator's opinion)
Not blinded
Blinding description
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
Babol University of Medical Sciences, Gangafrooz Street, Daneshgah Square, Babol, Mazandaran, Iran
City
Babol
Province
Mazandaran
Postal code
471764136
Approval date
2018-12-30, 1397/10/09
Ethics committee reference number
IR.MUBABOL.HRI.REC.1397.221

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
Sedation
Timepoint
Before laryngoscopy
Method of measurement
Ramsay sedation scale

2

Description
Blood pressure
Timepoint
Before prescribing the drug; before laryngoscopy; after intubation; 1, 3, 5, and 10 minutes after intubation and 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, and 10 minutes after intubation and 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, and 10 minutes after intubation and after surgical incision.

Method of measurement
Pulse oximeter

Intervention groups

1

Description
Dexmedetomidine (Imagen Pharmacy) 0.5 mcg/kg in 50 ml of normal saline within 10 minutes before intubation
Category
Treatment - Drugs

2

Description
Control group: : Fentanyl (Caspian Company) 1mcg/kg in 50 ml of normal saline within 10 minutes before intubation
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Ayatollah Rouhani Hospital
Full name of responsible person
Parviz Amri-maleh
Street address
Ganjafrooz Avenue, Daneshgah Square, Ruhani Hospital
City
Babol
Province
Mazandaran
Postal code
47176-47745
Phone
+98 11 3219 9592
Fax
+98 11 3219 0181
Email
pamrimaleh@yahoo.com
Web page address

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-maleh
Position
Associated Professor
Latest degree
Specialist
Other areas of specialty/work
Anesthesiology
Street address
Ayatollah Rouhani Hospital, Daneshgah Square, Ganjafrooz Avenue
City
Mazandaran
Province
Mazandaran
Postal code
47176-41367
Phone
+98 11 3233 8301
Email
pamrimaleh@yahoo.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Babol University of Medical Sciences
Full name of responsible person
Parviz Amri-maleh

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@yahoo.com

Person responsible for updating data

Contact
Name of organization / entity
Babol University of Medical Sciences
Full name of responsible person
Parviz Amri-maleh
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@yahoo.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
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