

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 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 Sciences

##### 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

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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**

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

**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,