

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

03 Jun 2026

### To compare the effect of intravenous Rapifen and Lidocaine to control hemodynamic responses in laryngoscopy and intubation

#### Protocol summary

##### Summary

The aim of this study is to compare the effect of intravenous Rapifen and Lidocaine to control hemodynamic responses in laryngoscopy and intubation. Its applied objective is to use a method that better controls blood pressure and heart rate in laryngoscopy and intubation. The main criterion for patients to include this study was age (15-60 years old). Also, the criteria to exclude this study are patients with narcotics addiction, cardiopulmonary diseases, hypertension (more than 140/90), chronic diseases using narcotics, and pregnant women. Sample population include 120 patients needing endotracheal intubation and surgery, admitting in Shahid Rajaei and Velayat hospitals of Qazvin. Patients divide into four groups (A, B, C, and D), randomly. Induction of anesthesia include; Fentanyl (1 microgram per kilogram) plus Midazolm (0/02 milligram per kilogram), and after two minutes, Nesdonal (5 milligram per kilogram) plus Atracurium (0/5 milligram per kilogram). In addition to induce the routine anesthesia; Group A, receive distilled water. Distilled water is placebo. Group B receive intravenous Lidocaine (1/5 milligram per kilogram), group C receive intravenous Rapifen (10 microgram per kilogram), and group D receive intravenous Lidocaine (1/5 milligram per kilogram) plus Rapifen (10 microgram per kilogram), 1/5 minutes before laryngoscopy and intubation. In each group, blood pressure and heart rate measure before sedation & induction, and 20 seconds & 5 minutes after laryngoscopy, respectively.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2014042117373N1**

Registration date: **2014-10-20, 1393/07/28**

Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2014-10-20, 1393/07/28

##### Registrant information

###### Name

Kambiz Boroojli

###### Name of organization / entity

Qazvin University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 28 1333 5800

###### Email address

kboroojli@qums.ac.ir

##### Recruitment status

###### Recruitment complete

##### Funding source

Qazvin University of Medical Sciences, Shahid Rajaie and Velayat hospitals

##### Expected recruitment start date

2014-07-23, 1393/05/01

##### Expected recruitment end date

2014-10-23, 1393/08/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

To compare the effect of intravenous Rapifen and Lidocaine to control hemodynamic responses in laryngoscopy and intubation

##### Public title

To compare the effect of intravenous Rapifen and Lidocaine to control hemodynamic responses in

laryngoscopy and intubation

### **Purpose**

Prevention

### **Inclusion/Exclusion criteria**

Inclusion criteria: patients with 15 years old to 60 years old

. Exclusion criteria: addiction : patients with heart disease : respiratory disease : hypertension( >140/90) : chronic disease with giving analgesic drugs : pregnancy

### **Age**

From **15 years** old to **60 years** old

### **Gender**

Both

### **Phase**

4

### **Groups that have been masked**

*No information*

### **Sample size**

Target sample size: **120**

### **Randomization (investigator's opinion)**

Randomized

### **Randomization description**

### **Blinding (investigator's opinion)**

Not blinded

### **Blinding description**

### **Placebo**

Used

### **Assignment**

Factorial

### **Other design features**

## **Secondary Ids**

empty

## **Ethics committees**

### 1

#### **Ethics committee**

##### **Name of ethics committee**

Qazvin University of Medical Sciences

##### **Street address**

Bahonar street , Qazvin University of Medical Sciences

##### **City**

Qazvin

##### **Postal code**

#### **Approval date**

2014-03-03, 1392/12/12

#### **Ethics committee reference number**

28/20/8498

## **Health conditions studied**

### 1

#### **Description of health condition studied**

General anesthesia

#### **ICD-10 code**

T 88.5

#### **ICD-10 code description**

Other complications of anesthesia

## **Primary outcomes**

### 1

#### **Description**

Blood pressure

#### **Timepoint**

Before sedation , before induction , 20 s after laryngoscopy , 5 minutes after laryngoscopy

#### **Method of measurement**

Blood pressure measurement device

### 2

#### **Description**

Heart rate

#### **Timepoint**

Before sedation , before induction , 20 s after laryngoscopy , 5 minutes after laryngoscopy

#### **Method of measurement**

Monitoring of heart rate device

## **Secondary outcomes**

empty

## **Intervention groups**

### 1

#### **Description**

In group A, patients receive routine anesthesia, and distilled water 1.5 minutes before laryngoscopy and intubation .Distilled water is placebo.

#### **Category**

Treatment - Drugs

### 2

#### **Description**

In addition to induce routine anesthesia; patients in group B receive intravenous Lidocaine (1.5 milligram per kilogram) 1.5 minutes before laryngoscopy and intubation

#### **Category**

Treatment - Drugs

### 3

#### **Description**

In addition to induce routine anesthesia; patients in group C receive intravenous Rapifen (10 microgram per kilogram) 1.5 minutes before laryngoscopy and intubation

#### **Category**

Treatment - Drugs

### 4

#### **Description**

In addition to induce routine anesthesia; patients in group D receive intravenous Lidocaine (1.5 milligram per kilogram) plus Rapifen (10 microgram per kilogram) 1.5

minutes before laryngoscopy and intubation

### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Qazvin University of Medical Sciences , Velayat hospital

##### Full name of responsible person

Kambiz Boroojli

##### Street address

Elahieh street , 22 bahman street , Taavon square , Qazvin

##### City

Qazvin

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Qazvin University of Medical Sciences

##### Full name of responsible person

Kambiz Boroojli

##### Street address

Elahieh street , 22 bahman street , Taavon square , Qazvin

##### City

Qazvin

##### Grant name

##### Grant code / Reference number

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

Yes

##### Title of funding source

Qazvin University of Medical Sciences

##### Proportion provided by this source

100

##### Public or private sector

*empty*

##### Domestic or foreign origin

*empty*

##### Category of foreign source of funding

*empty*

##### Country of origin

##### Type of organization providing the funding

*empty*

## Person responsible for general inquiries

#### Contact

##### Name of organization / entity

Qazvin University of Medical Sciences

##### Full name of responsible person

Kambiz Boroojli

##### Position

Anesthesia resident

#### Other areas of specialty/work

##### Street address

Elahieh street , 22 bahman street , Taavon square , Qazvin

##### City

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##### Postal code

##### Phone

+98 28033790620

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##### Email

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##### Web page address

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## Person responsible for scientific inquiries

#### Contact

##### Name of organization / entity

Qazvin University of Medical Sciences , Velayat hospital

##### Full name of responsible person

Alli Alizadeh

##### Position

Attend of anesthesia

##### Other areas of specialty/work

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## Person responsible for updating data

#### Contact

##### Name of organization / entity

Qazvin University of Medical Sciences , Velayat hospital

##### Full name of responsible person

Kambiz Boroojli

##### Position

Anesthesia resident

##### Other areas of specialty/work

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**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

*empty*

**Study Protocol**

*empty*

**Statistical Analysis Plan**

*empty*

**Informed Consent Form**

*empty*

**Clinical Study Report**

*empty*

**Analytic Code**

*empty*

**Data Dictionary**

*empty*