

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 Jul 2026

Comparison of the Hemodynamic Changes in Usage of Direct Intratracheal Intubation and Laryngeal Mask in Patients under General Anesthesia

Protocol summary

Summary

Objectives: In the present study we compare the usage of two methods for intubation (direct intratracheal intubation and laryngeal mask) to find the method with less hemodynamic effects in patients under general anesthesia. **Design:** In this clinical trial 200 patients who are candidate for surgery under general anesthesia will be randomly divided into two groups; the control group and the trial group (each group has 100 members). **Setting and conduct:** The patients in the control group will be intubated using direct intratracheal method after initiating general anesthesia and the patients in the trial group will be intubated using laryngeal mask after initiating general anesthesia. The types and dosage of anesthetic drugs are the same in both groups. **Major Inclusion and Exclusion criteria:** Patients who are candidate for surgery under general anesthesia with ASA class 1 in NPO condition, with neither urgent circumstances nor underline diseases. **Intervention:** Direct intratracheal intubation or laryngeal mask. **Main outcome measures (variables):** Mean heart rate, systolic blood pressure, diastolic blood pressure and arterial blood pressure before and after intubation will be compared with each other in the groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014110619037N3**
Registration date: **2014-11-17, 1393/08/26**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2014-11-17, 1393/08/26

Registrant information

Name

Mahdieh Yousef-Zanjani

Name of organization / entity

Qazvin University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 28 3333 6004

Email address

yusefi.mahdieh@yahoo.com

Recruitment status

Recruitment complete

Funding source

Investigator

Expected recruitment start date

2013-10-23, 1392/08/01

Expected recruitment end date

2014-12-06, 1393/09/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the Hemodynamic Changes in Usage of Direct Intratracheal Intubation and Laryngeal Mask in Patients under General Anesthesia

Public title

Comparison of the Hemodynamic Changes in Usage of Intratracheal Intubation and Laryngeal Mask in Patients under Anesthesia

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: Patients between 20 to 50 years of age who are candidate for surgery under general anesthesia and are in ASA class 1 (The American Society of Anesthesiologists Physical Status classification system): Normal healthy patients with no organic, physiologic, or psychiatric disturbance. Exclusion criteria: Patients who use anti-hypertensive, analgesic or sedative agents; patients who need urgent intubation; patients who are not NPO (nil per os); difficult intubation; diabetic patients.

Age

From **20 years** old to **50 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **200**

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Single blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features

The patients who enter the trial will be randomly selected for each groups of the study by Random Allocation.

Secondary Ids

empty

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

Ethics committee of Qazvin University of Medical Sciences

Street address

Shahid Bahonar Boulevard

City

Qazvin

Postal code**Approval date**

2014-06-12, 1393/03/22

Ethics committee reference number

28.20.8855

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

Heart rate instability due to intubation

ICD-10 code

-

ICD-10 code description

-

2**Description of health condition studied**

Blood pressure instability due to intubation

ICD-10 code

-

ICD-10 code description

-

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

Mean heart rate

Timepoint

1 minute before intubation and 1, 2, 3, 4, 5 and 10 minutes after intubation

Method of measurement

The monitor device

2**Description**

Mean systolic blood pressure

Timepoint

1 minute before intubation and 1, 2, 3, 4, 5 and 10 minutes after intubation

Method of measurement

The monitor device

3**Description**

Mean diastolic blood pressure

Timepoint

1 minute before intubation and 1, 2, 3, 4, 5 and 10 minutes after intubation

Method of measurement

The monitor device

4**Description**

Mean arterial blood pressure

Timepoint

1 minute before intubation and 1, 2, 3, 4, 5 and 10 minutes after intubation

Method of measurement

The monitor device

Secondary outcomes

1

Description

-

Timepoint

-

Method of measurement

-

Intervention groups

1

Description

First intervention group: Using of intubation tube for direct intubation from SUPA company, Iran, registered No. 24422

Category

Other

2

Description

Second intervention group: Using of laryngeal mask for intubation from Cerdas Seimbang Sdn. Bhd. company, Malaysia, registered No. 130601

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Velayat General Hospital

Full name of responsible person

Dr. Mahdi Ebtehaj

Street address

Taavon Square

City

Qazvin

2

Recruitment center

Name of recruitment center

Shahid Rajayi Hospital

Full name of responsible person

Dr. Mahdi Ebtehaj

Street address

Padegan Street

City

Qazvin

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Investigator

Full name of responsible person

Elaheh Kosari

Street address

Velayat Hospital, Taavon Square

City

Qazvin

Grant name

-

Grant code / Reference number

-

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

Yes

Title of funding source

Investigator

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

Person responsible for scientific inquiries

Contact

Name of organization / entity

Velayat Hospital

Full name of responsible person

Dr. Elaheh Kosari

Position

Anesthesiology Resident

Other areas of specialty/work

Street address

Taavon Square

City

Qazvin

Postal code

Phone

+98 28 3379 0620

Fax

Email

kosari1377@gmail.com

Web page address

Person responsible for updating data

Contact

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