

Clinical Trial Protocol

Iranian Registry of Clinical Trials

06 Jun 2026

comparison between Remifenil, lidocaine and fentanil on hemodynamic changes on CABG during laryngoscopy and tracheal intubation

Protocol summary

Summary

Since, uses of different drugs for attention of laryngoscopy and tracheal intubation response is controversy. The aim of this study is to compare the hemodynamic effects of remifentanyl, Lidocaine as a IV and spray versus fentanyl for tracheal intubation in patients for coronary artery bypass grafting (CABG). A randomized, double-blinded study, 100 patients for coronary artery bypass surgery in referral cardiac surgery are assessed. Subjects received in 5 groups: remifentanyl, 5 microgram/kg, Fentanyl, 8 micro/kg, and Lidocaine 1.5 mg / kg, Lidocaine 10% as a spray and routine group (fentanyl 5 micro gram per kg 3 minutes before laryngoscopy are used. Systolic, diastolic blood pressure, heart rate, mean arterial pressure are similar measured during before and after tracheal intubation; immediately, 1, 3, 5, 10, minutes after intubation. Patients were monitored by data scope for hemodynamic changes using electrocardiography. Data in groups compared with ANOVA test. P Value less than 0.05 is significant.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138905114492N1**

Registration date: **2009-04-04, 1388/01/15**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2009-04-04, 1388/01/15

Registrant information

Name

Ebrahim Nasiri formi

Name of organization / entity

Mazandaran University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Deputy of research of Mazandaran University of Medical Sciences
Univera

Expected recruitment start date

2009-04-04, 1388/01/15

Expected recruitment end date

2010-06-05, 1389/03/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

comparison between Remifenil, lidocaine and fentanil on hemodynamic changes on CABG during laryngoscopy and tracheal intubation

Public title

Comparison between drugs on hemodynamic changes during tracheal intubation for CABG

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion Criteria are: CABG candidate patients, 50-85 years old, ASA III, IV Exclusion Criteria are: Difficult Intubation, laryngoscopy and tracheal intubation time more than 30 second, more than two times tried for intubation, Sensitivity to local anesthetic drugs

Age

From **50 years** old to **85 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Randomized

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

Double blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features

routine group as a control group

Secondary Ids

empty

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

Mazandaran University of Medical Sciences

Street address

Moalem Square, Chancelar of research of Mazandaran
University of Medical Sciences

City

Sari

Postal code

4817844718

Approval date

2009-03-04, 1387/12/14

Ethics committee reference number

87-41 (2009/03/04)

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

Hemodynamic change, Local anesthesia, tracheal
intubation , CABG

ICD-10 code

-

ICD-10 code description

-

2**Description of health condition studied**

Atherosclerotic heart disease

ICD-10 code

I25.1

ICD-10 code description

Atherosclerotic heart disease

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

Systolic Blood pressure

Timepoint

from 2 to 5 minutes

Method of measurement

We used invasive arterial line blood pressure monitoring
with datascopes produced in USA

2**Description**

Diastolic Blood pressure

Timepoint

2-5 min

Method of measurement

We used invasive arterial line blood pressure monitoring
with datascopes produced in USA

3**Description**

Heart rate

Timepoint

2- 5 Min

Method of measurement

We used invasive arterial line blood pressure monitoring
with datascopes produced in USA

4**Description**

Premature ventricular contraction (PVC)

Timepoint

Before intubation, continuous monitoring after intubation
up to the 10th minute

Method of measurement

We used invasive arterial line blood pressure monitoring
with datascopes produced in USA

5**Description**

SPo2

Timepoint

2- 5 minutes interval

Method of measurement

Pulse Oximetry instrument

6**Description**

Mean arterial pressure

Timepoint

2-5 Min

Method of measurement

We used invasive arterial line blood pressure monitoring with datascopes produced in USA

Secondary outcomes

empty

Intervention groups

1

Description

Remifentanyl 0.5 microgram per kilogram , 3 min before laryngoscopy

Category

Treatment - Drugs

2

Description

Spray of 10% lidocaine 2 puff to supraglottic 3 min before laryngoscopy

Category

Treatment - Drugs

3

Description

Lidocaine IV 1.5 mg/kg 3 min before laryngoscopy

Category

Treatment - Drugs

4

Description

Fentanyl 8 micro gram per kilogram 3 min prior Laryngoscopy

Category

Treatment - Drugs

5

Description

Fentanyl 3-5 Micrograms per kilogram 3 min before laryngoscopy as routine or control group

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Hazrateh Fatemah Hospital (educational hospital and center of heart surgery hospital in Sari)

Full name of responsible person

Ebrahim Nasiri, MSc of anesthesiology and Academic faculty member

Street address

Dept of anesthesia, Operating room and emergency Medicine, Mazandaran University of medical

Sciences

City

Sari

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Mazandaran University of Medical Sciences

Full name of responsible person

Dr Enayati or Dr Haghshenas

Street address

Moalem Square, Deputy of research, Mazandaran University of Medical Sciences

City

Sari

Grant name

تحقیقات و آموزش

Grant code / Reference number

41

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

Yes

Title of funding source

Vice chancellor for research, Mazandaran 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

Mazandaran University of Medical Sciences

Full name of responsible person

Dr Mohammad reza Haghshenas

Position

Virologist, Deputy of research

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