

Clinical Trial Protocol

Iranian Registry of Clinical Trials

22 Jul 2026

Evaluation of a Correlation between the Time of Low Dose Fentanyl Injection and Hemodynamic Responses during Tracheal Intubation in Emam Khomeini Hospital

Protocol summary

Summary

This clinical trial was conducted to evaluate optimal time of injection of a small dose of fentanyl during anesthetic induction to attenuate circulatory responses to laryngoscopy and tracheal intubation. A total of 120 patients who scheduled for elective surgery were included in this study. The patients were randomly allocated to five groups. In groups II, III, IV, and V, the patients received fentanyl (2 microg/kg), 1, 3, 5, and 10 min before tracheal intubation, respectively. Group I patients did not receive fentanyl and served as the control group. Following induction with thiopental and atracurium an oral tracheal intubation was accomplished in each patient. Pulse rate, systolic, diastolic blood pressure, and mean arterial blood pressure were measured before the induction and 1 min after the intubation and changes were compared between groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201012215363N2**

Registration date: **2011-02-13, 1389/11/24**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2011-02-13, 1389/11/24

Registrant information

Name

Taraneh Naghibi

Name of organization / entity

Zanjan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 24 3347 2865

Email address

tnaghibi@zums.ac.ir

Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Sciences

Expected recruitment start date

2006-04-21, 1385/02/01

Expected recruitment end date

2007-04-21, 1386/02/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of a Correlation between the Time of Low Dose Fentanyl Injection and Hemodynamic Responses during Tracheal Intubation in Emam Khomeini Hospital

Public title

Evaluation of a Correlation between the Time of Low Dose Fentanyl Injection and Hemodynamic Responses during Tracheal Intubation

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: ASA class I or II, Age between 20- 65 year, scheduled to undergo elective surgery under general anesthesia Exclusion criteria: any history of hypertension, intestinal obstruction, cachexia, dehydration; cardiac, coronary, neurological, respiratory or renal dysfunction; Patients with difficult intubation

Age

From **20 years** old to **65 years** old

Gender

Both

Phase

1

Groups that have been masked

No information

Sample size

Target sample size: **120**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Tehran University of Medical Sciences

Street address

Faculty of medicine, Tehran University of Medical Sciences, Enghelab Sq, Tehran, Iran

City

Tehran

Postal code

Approval date

2006-02-23, 1384/12/04

Ethics committee reference number

841207

Health conditions studied

1

Description of health condition studied

circulatory change after intubation

ICD-10 code

I97.9

ICD-10 code description

Postprocedural disorder of circulatory system, unspecified

Primary outcomes

1

Description

heart rate

Timepoint

before induction, 1 minute after intubation

Method of measurement

ECG

2

Description

systolic blood pressure

Timepoint

before induction, 1 minute after intubation

Method of measurement

NIBP

3

Description

diastolic blood pressure

Timepoint

before induction, 1 minute after intubation

Method of measurement

NIBP

4

Description

mean blood pressure

Timepoint

before induction, 1 minute after intubation

Method of measurement

NIBP

Secondary outcomes

empty

Intervention groups

1

Description

Group II: In this group patients received fentanyl (2 microg/kg) (Fentanyl - Janseen cilag - Belgium) 1min before tracheal intubation. Following induction with thiopental (5mg/kg) (Thiopental - SANDOZ - Austria) and atracurium (0.5mg/kg) (Atracurium 25- Aburahhan - Iran) an oral tracheal intubation was accomplished in each patient. Then they ventilated with 50% nitrous oxide, 50% oxygen and 0.8% halothane.

Category

Treatment - Drugs

2

Description

Group I (control): Following induction with thiopental (5mg/kg) (Thiopental - SANDOZ - Austria) and atracurium (0.5mg/kg) (Atracurium 25- Aburahhan - Iran) an oral tracheal intubation was accomplished in each patient, then they ventilated with 50% nitrous oxide, 50% oxygen and 0.8% halothane.

Category

Treatment - Drugs

3

Description

Group III: In this group patients received fentanyl (2 microg/kg) (Fentanyl - Janseen cilag - Belgium) 3min before tracheal intubation. Following induction with thiopental (5mg/kg) (Thiopental - SANDOZ - Austria) and atracurium (0.5mg/kg) (Atracurium 25- Aburahhan - Iran) an oral tracheal intubation was accomplished in each patient. Then they ventilated with 50% nitrous oxide, 50% oxygen and 0.8% halothane.

Category

Treatment - Drugs

4

Description

Group IV: In this group patients received fentanyl (2 microg/kg) (Fentanyl - Janseen cilag - Belgium) 5min before tracheal intubation. Following induction with thiopental (5mg/kg) (Thiopental - SANDOZ - Austria) and atracurium (0.5mg/kg) (Atracurium 25- Aburahhan - Iran) an oral tracheal intubation was accomplished in each patient. Then they ventilated with 50% nitrous oxide, 50% oxygen and 0.8% halothane.

Category

Treatment - Drugs

5

Description

Group V: In this group patients received fentanyl (2 microg/kg) (Fentanyl - Janseen cilag - Belgium) 10min before tracheal intubation. Following induction with thiopental (5mg/kg) (Thiopental - SANDOZ - Austria) and atracurium (0.5mg/kg) (Atracurium 25- Aburahhan - Iran) an oral tracheal intubation was accomplished in each patient. Then they ventilated with 50% nitrous oxide, 50% oxygen and 0.8% halothane.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Emam Hospital

Full name of responsible person

Street address

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice- Chancellor for Research of Tehran University of Medical Sciences

Full name of responsible person

Dr Akhondzadeh

Street address

Rozbeh Hospital- Tehran- Iran

City

Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice- Chancellor for Research of Tehran 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

Zanjan University of Medical Sciences

Full name of responsible person

Dr Faramarz Dobakhti

Position

Phd, Assistant Professor

Other areas of specialty/work

Street address

Faculty of pharmacy- Zanjan University of Medical Sciences

City

Zanjan

Postal code

Phone

+98 982414273636

Fax

Email

fdobakhti@zums.ac.ir

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Zanjan university of medical sciences

Full name of responsible person

Dr Taraneh Naghibi

Position

Assistant Professor - Anesthesiologist

Other areas of specialty/work

Street address

Ayatollah mosavi hospital- Zanjan- Iran

City

Zanjan

Postal code**Phone**

+98 24 1424 2712

Fax**Email**

tnaghibi@zums.ac.ir

Web page address

Sciences

City

Zanjan

Postal code**Phone****Fax****Email****Web page address****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

Person responsible for updating data**Contact****Name of organization / entity**

Zanjan University of Medical Sciences

Full name of responsible person

Dr Faramarz Dobakhti

Position

Assistant Professor

Other areas of specialty/work**Street address**

school of pharmacy- Zanjan University of Medical