Clinical Trial Protocol
Iranian Registry of Clinical Trials

25 Oct 2026

Comparative study of the effectiveness of fentanyl with and without nitroglycerine spray on hemodynamic response due to laryngoscopy and endotracheal intubation

Protocol summary

Study aim

Copaarison of the effectiveness of fentanyl with and without nitroglycerine spray on hemodynamic response due to laryngoscopy and endotracheal intubation

Design

This study is a one-blinded clinical trial. The study population will be all patients referred to Imam Reza hospital of Kermanshah. 40 eligible patients will be selected conveniently and randomly assigned to two intervention groups.

Settings and conduct

This study that will be conducted in Imam Reza hospital of Kermanshah is a one-blinded one that Tthe data analyzer was kept blind to the allocation of study groups. All patients will be hydrated with 7 ml/kg of Ringerlactate prior to drug administration. Hemodynamic changes including heart rate, systolic and diastolic blood pressure are recorded prior to drug administration.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age between 20-60 years; No history of heart disease or stroke, high blood pressure, and drug use and addiction accidentally; Patients who have had laryngoscopy more than once Exclusion criteria: Patients with diabetes; The data analyzer was kept blind to the allocation of study groups

Intervention groups

The first intervention group will receive fentanyl 2 µg / kg. The second intervention group will receive two puffs of nitroglycerin spray (400 micrograms) with fentanyl 2 µg / kg for 5 min before tracheal intubation (anesthesia induction) and laryngoscopy intravenously for 30 seconds.

Main outcome variables

blood pressure, heart rate

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20130812014333N142**
Registration date: **2020-03-17, 1398/12/27**
Registration timing: **prospective**

Last update: **2020-03-17, 1398/12/27**
Update count: **0**

Registration date

2020-03-17, 1398/12/27

Registrant information

Name
Feizollah Foroughi
Name of organization / entity
kermanshah University of Medical Sciences
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Iran (Islamic Republic of)
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+98 83 1821 4653
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fforoughi@kums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-04-07, 1399/01/19

Expected recruitment end date

2020-07-09, 1399/04/19

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Comparative study of the effectiveness of fentanyl with and without nitroglycerine spray on hemodynamic response due to laryngoscopy and endotracheal intubation

Public title
Comparative study of the effectiveness of fentanyl with and without nitroglycerine spray on hemodynamic response due to laryngoscopy and endotracheal intubation

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Age between 20-60 years No history of heart disease or stroke, high blood pressure, and drug use and addiction accidentally
Exclusion criteria:
Patients who have had laryngoscopy more than once Patients with diabetes

Age
From **20 years** old to **60 years** old

Gender
Both

Phase
2-3

Groups that have been masked

- Data analyser

Sample size
Target sample size: **40**

Randomization (investigator's opinion)
Randomized

Randomization description
Using the random number table, patients are divided into three groups of 20. Each patient is assigned a 4-digit code based on the random number table, Based on the right number of patients code, the patients are divided into two groups. Patients whose last digit is 0, 2, 4, 6, 8 will be assigned to the first intervention group and patients whose last digit is 1,3,5, 7, 9 will be assigned to the second intervention group.

Blinding (investigator's opinion)
Single blinded

Blinding description
The data analyzer was kept blind to the allocation of study groups.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Kermanshah University of Medical Sciences
Street address
Building No.2, Shahid Beheshti, Vice Chancellor for Research Affairs, Kermanshah University of Medical Sciences
City
Kermanshah
Province
Kermanshah
Postal code
6715847141

Approval date
2020-03-02, 1398/12/12

Ethics committee reference number
ir.kums.rec.1398.1202

Health conditions studied

1

Description of health condition studied
General anesthesia

ICD-10 code
I46.9

ICD-10 code description
Cardiac arrest, cause unspecified

Primary outcomes

1

Description
blood pressure

Timepoint
Before starting the study, before laryngoscopy and intubation and at 10 and 1,3,5,7 minutes, after laryngoscopy and endotracheal intubation

Method of measurement
Using a barometer

2

Description
heart beat

Timepoint
Before starting the study, before laryngoscopy and intubation and at 10 and 1,3,5,7 minutes, after laryngoscopy and endotracheal intubation

Method of measurement
Using the pacemaker

Secondary outcomes

empty

Intervention groups

1

Description
The first intervention group will receive fentanyl 2 µg / kg
Category
Treatment - Drugs

2

Description
The second intervention group will receive two puffs of nitroglycerin spray (400 micrograms) with fentanyl 2 µg / kg for 5 min before tracheal intubation (anesthesia induction) and laryngoscopy intravenously for 30 seconds.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Emam Reza Hospital
Full name of responsible person
Javad Nazari
Street address
Emam Reza Hospital, Parastar Boulevard
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sajad.nazari90@yahoo.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Kermanshah University of Medical Sciences
Full name of responsible person
Dr. Farid Najafi
Street address
Building No.2, Shahid Beheshti, Vice Chancellor for Research Affairs, Kermanshah University of Medical Sciences
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fnajafi@kums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Kermanshah 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
Kermanshah University of Medical Sciences
Full name of responsible person
Javad Nazari
Position
Anesthesiology resident
Latest degree
Medical doctor
Other areas of specialty/work
Anesthesiology
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Person responsible for scientific inquiries

Contact
Name of organization / entity
Kermanshah University of Medical Sciences
Full name of responsible person
Dr. javad Aminisaman
Position
Member of Kermanshah University of Medical Sciences
Latest degree
Specialist
Other areas of specialty/work

Anesthesiology

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Person responsible for updating data

Contact

Name of organization / entity

Kermanshah University of Medical Sciences

Full name of responsible person

Javad Nazari

Position

Anesthesiology resident

Latest degree

Medical doctor

Other areas of specialty/work

Anesthesiology

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

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

Yes - There is a plan to make this available

Clinical Study Report

Not applicable

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

The main outcomes of the study will be shared.

When the data will become available and for how long

6 months

To whom data/document is available

If requested, results will be made available to other academic researchers

Under which criteria data/document could be used

Collected data is confidential and will not be shared with anyone else

From where data/document is obtainable

To receive the documentation, email send for update manager

What processes are involved for a request to access data/document

In a 15-day period, the documents will be sent e-mail

Comments