

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 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

Country

Iran (Islamic Republic of)

Phone

+98 83 1821 4653

Email address

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	
<u>1</u>	
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

<u>1</u>	
Description of health condition studied	General anesthesia
ICD-10 code	I46.9
ICD-10 code description	Cardiac arrest, cause unspecified

Primary outcomes

<u>1</u>	
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
<u>2</u>	
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

City

Kermanshah

Province

Kermanshah

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Phone

+98 83 3427 6306

Email

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