

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

A comparative study on the effect of fentanyl, morphine and methadone on hemodynamics of patients undergoing laryngoscopy and intubation in chronic users taking drugs by inhaler

Protocol summary

Study aim

A comparative study on the effect of fentanyl, morphine and methadone on hemodynamics of patients undergoing laryngoscopy and intubation in chronic users taking drugs by inhaler

Design

this is a one-blinded clinical trial. The study population will be included all patients refer to Imam Reza hospital of Kermanshah city. A total of eligible patients will be selected conveniently and randomly will be assigned in 3 intervention groups.

Settings and conduct

This study, which will be conducted at Imam Reza hospital of Kermanshah city is one-blinded one that the participants will not know what medicine they will receive. patients will be kept blinded to the study groups, does of the medicine and pharmaceutical manufacturer.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients taking drugs by inhaler; Under 65 years old Exclusion criteria: History of heart disease; History of high blood pressure, diabetes and other systemic diseases; Patients who take drugs orally

Intervention groups

The first intervention group will receive intravenous 0.6 mg fentanyl. The second intervention group will receive intravenous 0.6 mg Methadone. The third intervention group will receive intravenous 0.6 mg Morphine. After 2 minutes oxygenation with 100% oxygen, all patients undergo laryngoscopy with Macintosh curved blades 4 or 5 and the intubation will be fitted with a Cuffed tube for oral intubation

Main outcome variables

blood pressure, Pulse

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20100101002946N10**

Registration date: **2018-10-28, 1397/08/06**

Registration timing: **prospective**

Last update: **2018-10-28, 1397/08/06**

Update count: **0**

Registration date

2018-10-28, 1397/08/06

Registrant information

Name

Mitra Yari

Name of organization / entity

Kermanshah University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 83 1427 6310

Email address

myari@kums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-11-06, 1397/08/15

Expected recruitment end date

2019-01-05, 1397/10/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A comparative study on the effect of fentanyl, morphine and methadone on hemodynamics of patients undergoing laryngoscopy and intubation in chronic users taking drugs by inhaler		Kermanshah
Public title		Province
A comparative study on the effect of fentanyl, morphine and methadone on hemodynamics of patients		Kermanshah
Purpose		Postal code
Treatment		6715847141
Inclusion/Exclusion criteria		Approval date
Inclusion criteria:		2018-10-10, 1397/07/18
Patients taking drugs by inhaler Under 65 years old		Ethics committee reference number
Exclusion criteria:		ir.kums.rec.1397.563
History of heart disease History of high blood pressure, diabetes and other systemic diseases Patients who take drugs orally		
Age		Health conditions studied
To 65 years old		<u>1</u>
Gender		Description of health condition studied
Both		Tracheal intubation
Phase		ICD-10 code
2-3		Y84.8
Groups that have been masked		ICD-10 code description
Participant		Other medical procedures as the cause of abnormal reaction of the patient, or of later complication, without mention of misadventure at the time of the procedure
Sample size		Primary outcomes
Target sample size: 150		<u>1</u>
Randomization (investigator's opinion)		Description
Randomized		blood pressure
Randomization description		Timepoint
Randomly Individually by random number table via code receipt		Immediately and 5 minutes after laryngoscopy and intubation
Blinding (investigator's opinion)		Method of measurement
Single blinded		Using the pressure gauge
Blinding description		<u>2</u>
In this study, patients were blinded to the dosage of the drug and the manufacturer of the drug in comparison to the study groups		Description
Placebo		Pulse
Not used		Timepoint
Assignment		Immediately and 5 minutes after laryngoscopy and intubation
Parallel		Method of measurement
Other design features		Using Holter Monitoring
Secondary Ids		Secondary outcomes
empty		empty
Ethics committees		Intervention groups
<u>1</u>		<u>1</u>
Ethics committee		Description
Name of ethics committee		The first intervention group will receive intravenous 0.6 mg fentanyl. After 2 minutes oxygenation with 100% oxygen, patients undergo laryngoscopy with Macintosh curved blades 4 or 5 and the intubation will be fitted with a Cuffed tube for oral intubation
Ethics committee of Kermanshah University of Medical Sciences		Category
Street address		Treatment - Drugs
Vice Chancellor for Research Affairs, Kermanshah University of Medical Sciences, Building No.2, Shahid Beheshti		
City		

2

Description

The second intervention group will receive intravenous 0.6 mg Methadone. After 2 minutes oxygenation with 100% oxygen, patients undergo laryngoscopy with Macintosh curved blades 4 or 5 and the intubation will be fitted with a Cuffed tube for oral intubation

Category

Treatment - Drugs

3

Description

The third intervention group will receive intravenous 0.6 mg Morphine. After 2 minutes oxygenation with 100% oxygen, patients undergo laryngoscopy with Macintosh curved blades 4 or 5 and the intubation will be fitted with a Cuffed tube for oral intubation

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Emam Reza Hospital

Full name of responsible person

Majid Mosadegh

Street address

Emam Reza Hospital, Parastar Boulevard

City

Kermanshah

Province

Kermanshah

Postal code

6715847141

Phone

+98 83 3427 6309

Email

majidmosadegh4@gmail.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

Vice Chancellor for Research Affairs, Kermanshah University of Medical Sciences, Building No.2, Shahid Beheshti

City

Kermanshah

Province

Kermanshah

Postal code

6715847141

Phone

+98 83 3836 0014

Email

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

Majid Mosadegh

Position

Resident of Anesthesia

Latest degree

Medical doctor

Other areas of specialty/work

Anesthesiology

Street address

Emam Reza Hospital, Parastar Boulevard

City

Kermanshah

Province

Kermanshah

Postal code

6715847141

Phone

+98 83 3427 6309

Email

majidmosadegh4@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Kermanshah University of Medical Sciences

Full name of responsible person

Dr. Mitra Yari

Position

Faculty Member of Kermanshah University of Medical Sciences

Latest degree

Specialist
Other areas of specialty/work
Anesthesiology
Street address
Emam Reza Hospital, Parastar Boulevard
City
Kermanshah
Province
Kermanshah
Postal code
6715847141
Phone
+98 83 3427 6306
Email
myari@kums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity
Kermanshah University of Medical Sciences
Full name of responsible person
Majid Mosadegh
Position
Resident of Anesthesia
Latest degree
Medical doctor
Other areas of specialty/work
Anesthesiology
Street address
Emam Reza Hospital, Parastar Boulevard
City
Kermanshah
Province
Kermanshah
Postal code
6715847141
Phone

+98 83 3427 6306

Email
majidmosadegh4@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

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