

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

23 Jun 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

#### Public title

A comparative study on the effect of fentanyl, morphine and methadone on hemodynamics of patients

#### Purpose

Treatment

#### Inclusion/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

#### Age

To **65 years** old

#### Gender

Both

#### Phase

2-3

#### Groups that have been masked

- Participant

#### Sample size

Target sample size: **150**

#### Randomization (investigator's opinion)

Randomized

#### Randomization description

Randomly Individually by random number table via code receipt

#### Blinding (investigator's opinion)

Single blinded

#### Blinding description

In this study, patients were blinded to the dosage of the drug and the manufacturer of the drug in comparison to the study groups

#### Placebo

Not 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

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

###### City

Kermanshah

###### Province

Kermanshah

###### Postal code

6715847141

###### Approval date

2018-10-10, 1397/07/18

###### Ethics committee reference number

ir.kums.rec.1397.563

### Health conditions studied

#### 1

##### Description of health condition studied

Tracheal intubation

##### ICD-10 code

Y84.8

##### ICD-10 code description

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

### Primary outcomes

#### 1

##### Description

blood pressure

##### Timepoint

Immediately and 5 minutes after laryngoscopy and intubation

##### Method of measurement

Using the pressure gauge

#### 2

##### Description

Pulse

##### Timepoint

Immediately and 5 minutes after laryngoscopy and intubation

##### Method of measurement

Using Holter Monitoring

### Secondary outcomes

empty

### Intervention groups

#### 1

##### Description

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

##### Category

Treatment - Drugs

## 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

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##### 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

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**Email**

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**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**

**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**

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