# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

18 Sep 2026

## Comparison of the quality of awake intubation with fiber optics in patients receiving dexmedetomidine with midazolam and fentanyl in Rasoul-e-Akram Hospital in 2016-17

## Protocol summary

**Study aim**

The quality of awake intubation with fiber optic is compared in patients receiving dexmedetomidine or midazolam and fentanyl in Rasoul-e-Akram Hospital in 1395-96.

**Design**

Clinical trial with control group, with parallel groups, double-blind, randomized,

**Settings and conduct**

Patients undergoing elective surgery at Rasoul-e-Akram Hospital in Tehran in 1395-1959 were studied. Using the table of random numbers, patients are divided into two groups of D and F. Group D are individuals who receive 1mcg / kg of dexmedetomidine infusion within 10 minutes and then receive 0.5 mcg / kg / h. Group F are people who receive 2 mcg / kg fentanyl and 1 mg midazolam IV. After reaching the peak of the effect of the drug, intubation with fiber opeptic by one third-year anesthesia assistant, not aware of the type of the prescribed drug.

**Participants/Inclusion and exclusion criteria**

Inclusion criteria: Age range 20 to 60 years ASA grade 1-2 Candidate for elective surgical operation in Rasoule-Akram hospital Candidate for awake intubation Exclusion criteria: Pregnant women Patients not able to collaborate (intellectual disability, low awareness, ...) Patients with A-V block in ECG Patients addicted to drugs of abuse or analgesics History of allergic reaction to each of the drugs under study Emergency operation Heart failure Uncontrolled asthma Incidence of adverse effects during study (including laryngospasms, bronchospasm, Ramsey scale >4 , any kind of hemodynamic changes requiring pharmaceutical intervention)

**Intervention groups**

Group D receive infusions of 1mcg / kg of trimodimide dosage in 10 minutes and then continued at 0.5 mcg / kg / h. Group F patients receive 2mcg / kg fentanyl and 1 mg midazolam IV.

**Main outcome variables**

Hemodynamic status; Spo2; FOB (fiber optics intubation) duration; frequency of attempts for FOB

## General information

**Reason for update**

**Acronym**

**IRCT registration information**

IRCT registration number: **IRCT20161220031487N9**
Registration date: **2018-04-27, 1397/02/07**
Registration timing: **retrospective**

Last update: **2018-04-27, 1397/02/07**
Update count: **0**

**Registration date**

2018-04-27, 1397/02/07

**Registrant information**

**Name**

مهرداد Mesbah kiaei

**Name of organization / entity**

Iran University of Medical Sciences

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Iran (Islamic Republic of)

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**Recruitment status**

**Recruitment complete**

**Funding source**

**Expected recruitment start date**

2017-12-21, 1396/09/30

**Expected recruitment end date**

2018-03-20, 1396/12/29

**Actual recruitment start date**
empty
**Actual recruitment end date**
empty
**Trial completion date**
empty

**Scientific title**
Comparison of the quality of awake intubation with fiber optics in patients receiving dexmedetomidine with midazolam and fentanyl in Rasoul-e-Akram Hospital in 2016-17

**Public title**
Comparison of two treatments for improving the outcomes in awake intubation
**Purpose**
Treatment
**Inclusion/Exclusion criteria**
**Inclusion criteria:**
Age range 20 to 60 years ASA grade 1-2 Candidate for elective surgical operation in Rasoule-Akram hospital Candidate for awake intubation
**Exclusion criteria:**
Pregnant women Patients not able to collaborate (intellectual disability, low awareness, ...) Patients with A-V block in ECG Patients addicted to drugs of abuse or analgesics History of allergic reaction to each of the drugs under study Emergency operation Heart failure Uncontrolled asthma Incidence of adverse effects during study (including laryngospasms, bronchospasm, Ramsey scale >4 , any kind of hemodynamic changes requiring pharmaceutical intervention)
**Age**
From **20 years** old to **60 years** old
**Gender**
Both

**Phase**
2-3
**Groups that have been masked**

- Participant
- Care provider

**Sample size**
Target sample size: **52**
More than 1 sample in each individual
Number of samples in each individual: **3**
After entering the operation room and before the administration of the drug, at the time of the maximizing the effect of drug medication (15 minutes for the dexmedetomidine and 5 minutes for fentanyl and midazolam) and the third immediately after the intubation
Actual sample size reached: **52**
More than 1 sample in each individual
Actual sample size in each individual: **3**
**Randomization (investigator's opinion)**
Randomized
**Randomization description**
At first, explanations about the method of work, as well as the advantages and disadvantages of both groups, are given to the patient, and they will be informed that they will be allocated to one of the two groups randomly. After receiving the patients' informed consent, using a table of random numbers, patients are randomly allocated in one of the D and F groups. Due to the fact that the syringes will be in equal numbers (shots) in both groups and the syringes are not labeled, the patient will not be aware of the type of the drug being injected.
**Blinding (investigator's opinion)**
Double blinded
**Blinding description**
The patient is unaware of the group in which he or she is allocated and the type of the medication he is receiving. After maximizing the effect of medication, the intubation was performed with oral fiber optic by a third-year anesthesia resident, without knowing the prescription drug type.
**Placebo**
Not used
**Assignment**
Parallel
**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

**Ethics committee**
**Name of ethics committee**
Ethics committee of Iran University of Medical Sciences
**Street address**
Between Sheykh Fazlollah highway and Chamran highway, Hemmat highway
**City**
Tehran
**Province**
Tehran
**Postal code**
1449614535
**Approval date**
2017-08-25, 1396/06/03
**Ethics committee reference number**
IR.IUMS.FMD.REC1396.9311174006

## Health conditions studied

### 1

**Description of health condition studied**
Failed or difficult intubation
**ICD-10 code**
T88.4
**ICD-10 code description**
Failed or difficult intubation

## Primary outcomes

**1**

**Description**
Heart rate
**Timepoint**
Before premedication, after premedication and after intubation
**Method of measurement**
Using patient monitoring system

**2**

**Description**
Blood pressure
**Timepoint**
Before premedication, after premedication and after intubation
**Method of measurement**
Using patient monitoring system

**3**

**Description**
Arterial blood gas analysis
**Timepoint**
Before premedication, after premedication and after intubation
**Method of measurement**
Arterial blood gas analysis system

**4**

**Description**
Analgesia
**Timepoint**
Before premedication, after premedication and after intubation
**Method of measurement**
Ramsey sedation scale

## Secondary outcomes

**1**

**Description**
Attempts for awake intubation with fiber optic
**Timepoint**
During intubation
**Method of measurement**
Counting the number of attempts for intubation

## Intervention groups

**1**

**Description**
Intervention group: infusions of 1mcg / kg of trimodimide dosage in 10 minutes and then continued at 0.5 mcg / kg / h
**Category**
Treatment - Drugs

**2**

**Description**
Control group: 2 mcg / kg fentanyl and 1 mg midazolam IV.
**Category**
Treatment - Drugs

## Recruitment centers

**1**

**Recruitment center**
**Name of recruitment center**
Rassoul-e-Akram hospital
**Full name of responsible person**
Valiollah Hassani
**Street address**
Niyayesh St., Sattarkhan st.
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## Sponsors / Funding sources

**1**

**Sponsor**
**Name of organization / entity**
Iran University of Medical Sciences
**Full name of responsible person**
Seyed Kazem Malakouti
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Between Sheykh Fazlollah and Chamran highway, Hemmat highway
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research@iums.ac.ir
**Grant name**
**Grant code / Reference number**
**Is the source of funding the same sponsor organization/entity?**
Yes
**Title of funding source**
Iran 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**

Iran University of Medical Sciences

**Full name of responsible person**

Valiollah Hassani

**Position**

Professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Anesthesiology

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## Person responsible for updating data

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**Position**

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## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be a plan to make this available

**Study Protocol**

No - There is not a plan to make this available

**Statistical Analysis Plan**

No - There is not a plan to make this available

**Informed Consent Form**

No - There is not a plan to make this available

**Clinical Study Report**

Undecided - It is not yet known if there will be a plan to make this available

**Analytic Code**

Undecided - It is not yet known if there will be a plan to make this available

**Data Dictionary**

Undecided - It is not yet known if there will be a plan to make this available