Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Jun 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

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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
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Full name of responsible person
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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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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