Clinical Trial Protocol
Iranian Registry of Clinical Trials

31 May 2026

Comparative study of the effect of "ketamine-midazolam" with "ketamine-dexmedetomidine" on sedation, pain, and hemodynamic changes in patients candidate for fiberoptic bronchoscopy

Protocol summary

Study aim
Determining and comparing the effect of "ketamine-midazolam" with "ketamine-dexmedetomidine" on sedation, pain, and hemodynamic changes in patients candidate for fiberoptic bronchoscopy

Design
A randomized double-blind clinical trial, with the parallel groups

Settings and conduct
This randomized double-blind clinical trial is carried out at Al-Zahra Hospital in Isfahan. In this study, 66 candidates for fiberoptic bronchoscopy will be admitted and randomly divided into 2 parallel groups. Then for these two groups, "ketamine-midazolam" and "ketamine-dexmedetomidine" will be administered, respectively.

Participants/Inclusion and exclusion criteria
Inclusion criteria include patients who are candidates for bronchoscopy and ASA I and II. Exclusion criteria included taking painkillers and opioids 24 hours before surgery, taking beta-blocker before the study, muscle weakness, drug allergies, and asthma, as well as patients with a history of cardiovascular disease, kidney disease, liver disease, chronic respiratory disease, immunodeficiency, people who have consumed alcohol 24 hours before surgery, and people with heart blocks and conduction disorders of the heart.

Intervention groups
First, for all patients, 2% lidocaine(Caspian-Tamin Company) is sprayed onto the vocal cords. For all patients, nasal oxygen with a flow of 2 liters per minute is installed. Patients in the first group receive 1 mg/kg ketamine(Caspian-Tamin Company) and 1 µg/kg dexmedetomidine(Caspian-Tamin Company) for 10 minutes and the infusion of 0.5 mg/min ketamine and 0.5 µg/kg dexmedetomidine. Patients in the second group receive 1 mg/kg ketamine and 2.5 mg midazolam (Caspian-Tamin Company) over ten minutes and are also given an infusion of 0.5 mg/min ketamine and a 25% starting dose of midazolam.

Main outcome variables
Sedation level; pain and hemodynamic parameters

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20200825048515N13**
Registration date: **2020-12-03, 1399/09/13**
Registration timing: **registered_while_recruiting**

Last update: **2020-12-03, 1399/09/13**
Update count: **0**

Registration date
2020-12-03, 1399/09/13

Registrant information

Name
Asieh Maghami Mehr

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-10-22, 1399/08/01

Expected recruitment end date
2021-04-20, 1400/01/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparative study of the effect of "ketamine-midazolam" with "ketamine-dexmedetomidine" on sedation, pain, and hemodynamic changes in patients candidate for fiberoptic bronchoscopy

Public title

Comparing the effect of "ketamine-midazolam" with "ketamine-dexmedetomidine" on hemodynamic changes in patients candidate for fiberoptic bronchoscopy

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients candidate for bronchoscopy The American Society of Anesthesiologists (ASA) Physical Status Classification equal I or II Being consent to participate in the study

Exclusion criteria:

Taking painkillers and opioids 24 hours before surgery Taking beta-blockers before the study Allergy to medications Asthma History of cardiovascular disease History of kidney disease History of liver disease History of chronic respiratory disease History of immunodeficiency Consuming alcohol 24 hours before surgery People with heart block and conduction disorders Having muscle weakness

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

2-3

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **66**

Randomization (investigator's opinion)

Not randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

In a double-blind trial, two drug-combinations will be prepared by the anesthesiologist before the intervention begins. All medicines will be provided in the same volume with the aid of distilled water. These syringes will be labeled and given to the researcher on a daily basis, and they will be administered without knowing the type of each drug. In addition, the patient (due to lack of consciousness) will not know the type of intervention. The statistical analyst will not be aware of the type of intervention.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Isfahan University of Medical Sciences

Street address

Hezar Jarib Ave, Azadi Square.

City

Isfahan

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Isfehan

Postal code

8174673461

Approval date

2020-08-08, 1399/05/18

Ethics committee reference number

IR.MUI.MED.REC.1399.376

Health conditions studied

1

Description of health condition studied

Bronchoscopy

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Sedation level

Timepoint

Two minutes after bolus injection

Method of measurement

Ramsay Sedation Scale

2

Description

Pain

Timepoint

Immediately, 10, 20 and 30 minutes after consciousness

Method of measurement

Visual Analog Scale (VAS)

3

Description

Blood pressure

Timepoint

Before the intervention, immediately, 10, 20 and 30 minutes after the intervention

Method of measurement

Monitoring device

4

Description

Heart rate

Timepoint

Before the intervention, immediately, 10, 20 and 30 minutes after the intervention

Method of measurement

Monitoring device

5

Description

Oxygen saturation percentage (SPO2)

Timepoint

Before the intervention, immediately, 10, 20 and 30 minutes after the intervention

Method of measurement

Monitoring device

Secondary outcomes

empty

Intervention groups

1

Description

First intervention group: First, for all patients, 2% lidocaine(Caspian-Tamin Company) is sprayed onto the vocal cords. For all patients, nasal oxygen with a flow of 2 liters per minute is installed. Patients in the first intervention group receive 1 mg/kg ketamine(Caspian-Tamin Company) and 1 µg/kg dexmedetomidine(Caspian-Tamin Company) for 10 minutes and the infusion of 0.5 mg/min ketamine and 0.5 µg/kg dexmedetomidine.

Category

Treatment - Drugs

2

Description

Second intervention group: First, for all patients, 2% lidocaine (Caspian-Tamin Company) is sprayed onto the vocal cords. For all patients, nasal oxygen with a flow of 2 liters per minute is installed. Patients in the second group receive 1 mg/kg ketamine (Caspian-Tamin Company) and 2.5 mg midazolam (Caspian-Tamin Company) over ten minutes and are also given an infusion of 0.5 mg/min ketamine and a 25% starting dose of midazolam.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Al-Zahra Hospital

Full name of responsible person

Behzad Nazemroaya

Street address

Anesthesiology Department, Al-Zahra Hospital, Hezar Jerib Street

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Shaghayegh Haghjoo Javanmard

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Vice Chancellor for Research, School of Medicine, Hezar Jarib Street, Isfahan.

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

No

Title of funding source

Isfahan 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
Esfahan University of Medical Sciences

Full name of responsible person
Behzad Nazemroaya

Position
Associate Professor

Latest degree
Specialist

Other areas of specialty/work
Anesthesiology

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Person responsible for scientific inquiries

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Esfahan University of Medical Sciences

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Position
Associate Professor

Latest degree
Specialist

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Person responsible for updating data

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Position
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Medical doctor

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD
There is no further information

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
No - There is not a plan to make this available

Analytic Code
No - There is not a plan to make this available

Data Dictionary
No - There is not a plan to make this available