Clinical Trial Protocol
Iranian Registry of Clinical Trials

02 Jun 2026

The comparison of the effect of sedative of Dexmedetomidine and Fentanyl in comparison with Ketamine and Fentanyl in participants undergoing colonoscopy

Protocol summary

Study aim
The comparison of the effect of sedative of Dexmedetomidine and Fentanyl with Ketamine and Fentanyl in participants undergoing colonoscopy

Design
Clinical trials with a control group with parallel, randomized groups, Group 1: Treated with Ketamine and Fentanyl, Group 2: Dexmedetomidine and Fentanyl, randomization method Simple randomization, randomization unit: Individual, randomization tool: Random number table, no blinded, The total sample size of 70 patients candidates for elective colonoscopy, clinical trial phase: 2.

Settings and conduct
Sina hospital in Tehran is the location of the study. Colonoscopy is a standard and common method for the diagnosis and screening, treatment and prevention of many colon diseases that can be performed in some centers without analgesic sedation. The aim of the study was the comparison of the effect of sedative of Dexmedetomidine and Fentanyl in comparison with Ketamine and Fentanyl in patients undergoing colonoscopy. Patients who were candidates for elective colonoscopy are included in this study. Group 1: Treated with Ketamine and Fentanyl, Group 2: Dexmedetomidine and Fentanyl, the total sample size of 70 patients, no blinded.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Participants with ASA grade I and II and candidates for elective colonoscopy. Exclusion criteria: Participants with complete heart block, liver failure, severe heart failure.

Intervention groups
Group 1: Treated with Ketamine and Fentanyl, Group 2: Dexmedetomidine and Fentanyl.

Main outcome variables
Relaxation; Pain.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20170805035510N5**
Registration date: **2019-07-28, 1398/05/06**
Registration timing: **retrospective**

Last update: **2019-07-28, 1398/05/06**
Update count: **0**

Registration date
2019-07-28, 1398/05/06

Registrant information

Name
Pejman Pourfakhr

Name of organization / entity
Tehran University of Medical Sciences

Country
Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-04-21, 1397/02/01

Expected recruitment end date
2019-01-21, 1397/11/01

Actual recruitment start date
2018-04-21, 1397/02/01

Actual recruitment end date
2019-01-21, 1397/11/01

Trial completion date

2019-03-16, 1397/12/25

Scientific title
The comparison of the effect of sedative of Dexmedetomidine and Fentanyl in comparison with Ketamine and Fentanyl in participants undergoing colonoscopy

Public title
Determination of the effect of sedative of Dexmedetomidine and Fentanyl with Ketamine and Fentanyl in participants undergoing colonoscopy

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Patients wwith anesthetic condition ASA Class I, II
Exclusion criteria:
Patients with complete heart block Liver failure Severe heart failure

Age
No age limit

Gender
Both

Phase
2

Groups that have been masked
No information

Sample size
Target sample size: **70**
Actual sample size reached: **70**

Randomization (investigator's opinion)
Randomized

Randomization description
Randomization method: Simple randomization, randomization unit: individual, randomization tool: random number table. Patients using odd and even numbers of random numbers will allocate in two groups: treated with ketamine and fentanyl. Group 2: Dexedtomodine and fentanyl.

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
کمیته اخلاق دانشگاه علوم پزشکی و خدمات درمانی تهران
Street address
Tehran University of Medical Sciences, Central Building, Ghods Ave., Keshavarz Blvd.
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Tehran
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Approval date
2017-08-09, 1396/05/18

Ethics committee reference number
IR.TUMS.MEDICINE.REC.1396.3131

Health conditions studied

1

Description of health condition studied
Participants candidates for colonoscopy dignosis

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Sedation

Timepoint
During colonoscopy and one minute after colonoscopy

Method of measurement
Visual Analogue Scale (VAS)

2

Description
Pain

Timepoint
One minute after colonoscopy

Method of measurement
Visual Analogue Scale (VAS)

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Combination of Ketamine and Fentanyl, Once before colonoscopy the dosage was injectable ketamine (ketamine hydrochloride 500 mg / ml or 0.5 mg/kg) and fentanyl (fentanyl 0.5 mg/ml 10 or µg/kg). ketamine acts as a selective antagonist of the NMDA receptor, an ionotropic glutamate receptor. Fentanyl provides some of the effects typical of other opioids through its agonism of the opioid receptors.

Category
Treatment - Drugs

2

Description
Control group: Control group: The combination of doxedemotomidine and fentanyl was administered once prior to colonoscopy by dose of 1 mg / kg dx dimethomidine and 1 µg / kg fentanyl intravenously. Dexmedetomidine, sold under the Precedex brand among others, is a reduction in thirst, sedation, and pain medications. Fentanyl through opioid receptor agonists provides some of the commonality of other drugs.

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Sina hospital

Full name of responsible person
Pejman Pourfakhr

Street address
Sina hospital, Hasan abad Square, Imam Khomeini St.

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Tehran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Tehran University of Medical Sciences

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
Tehran 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
Tehran University of Medical Sciences

Full name of responsible person
Pejman Pourfakhr

Position
Assistant Professor

Latest degree
Specialist

Other areas of specialty/work
Anesthesiology

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Person responsible for scientific inquiries

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Full name of responsible person
Pejman Pourfakhr

Position
Assistant Professor

Latest degree
Specialist

Other areas of specialty/work
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Person responsible for updating data

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Name of organization / entity

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Full name of responsible person

Pejman Pourfakhr

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

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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

No more 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