Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

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

Protocol summary

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

Design
Clinical trials with a hospital-based and pragmatic control group with parallel, randomized groups, Group 1: Treated with Propofol 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
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 Propofol and Fentanyl in patients undergoing colonoscopy. Patients referred to the Sina hospital who was candidates for elective colonoscopy. Group 1: Treated with Ketamine and Fentanyl, Group 2: Dexmedetomidine and Fentanyl, randomization method Simple randomization, randomization tool: Random number table, The total sample size of 70 patients.

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 Propofol and Fentanyl, Group 2: Dexmedetomidine and Fentanyl.

Main outcome variables
Relaxation; Pain.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20170805035510N4**
Registration date: **2019-05-22, 1398/03/01**
Registration timing: **retrospective**

Last update: **2019-05-22, 1398/03/01**
Update count: **0**

Registration date
2019-05-22, 1398/03/01

Registrant information

Name
Pejman Pourfakhr

Name of organization / entity
Tehran University of Medical Sciences

Country
Iran (Islamic Republic of)

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+98 21 4466 3963

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pourfakhr@tums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-05-23, 1397/03/02

Expected recruitment end date
2019-03-02, 1397/12/11

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date

empty

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

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

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
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**

Randomization (investigator's opinion)
Randomized

Randomization description
Randomization method: Simple randomization, randomization unit: individual, randomization tool: random number table.

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
Ethics Committee of Tehran University of Medical Sciences and Health services
Street address
Tehran University of Medical Sciences, Central Building, Ghods Ave., Keshavarz Blvd.
City
Tehran
Province
Tehran
Postal code
1417653761

Approval date
2017-07-02, 1396/04/11

Ethics committee reference number
IR.TUMS.MEDICINE.REC.1396.2762

Health conditions studied

1

Description of health condition studied
Participants candidates for colonoscopy for diagnosis any disease

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Sedation

Timepoint
After colonoscopy

Method of measurement
Visual Analogue Scale (VAS)

Secondary outcomes

1

Description
Pain

Timepoint
After colonoscopy

Method of measurement
Visual Analogue Scale (VAS)

Intervention groups

1

Description
Intervention group: Combination of Propofol and Fentanyl, Once before colonoscopy the dosage was injectable ketamine Propofol 500 mg/ml) and fentanyl (fentanyl 1 µg/kg). Propofol, as Diprivan among other names, is a short-acting medication that results in a decreased level of consciousness and lack of memory for events. Fentanyl provides some of the effects typical of other opioids through its agonism of the opioid receptors.

Category
Treatment - Drugs

2

Description
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.

City

Tehran

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1417653761

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+98 21 81631

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pourfakhr@tums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Seyedeh Elham Kavousi

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Tehran University of Medical Sciences, Central Building, Ghods Ave., Keshavarz Blvd

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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

Street address

Sina hospital, Hasan abad square, Emam Khomeini Ave.

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Person responsible for scientific inquiries

Contact

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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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Position
Associate professor

Latest degree
Specialist

Other areas of specialty/work
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is 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
Yes - There is 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

Title and more details about the data/document
Print article

When the data will become available and for how long
8 months

To whom data/document is available
Medical students

Under which criteria data/document could be used
Print article

From where data/document is obtainable
Pejman Pourfakhr

What processes are involved for a request to access data/document
Question

Comments