Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Investigation of hemodynamic effects of two combinations of Propofol-Fentanyl and Propofol- Lidocaine in patients undergoing upper endoscopy

Protocol summary

Study aim

By understanding the hemodynamic effects of Propofol-Fentanyl and Propofol-Lidocaine in patients undergoing endoscopy, a combination can be used during endoscopy that makes patients less prone to hemodynamic changes.

Design

Clinical trial with 2 groups of Fentanyl and Lidocaine, with parallel groups, single-blind, randomized, phase 3 on 198 patients. R block statistical software is used for block randomization.

Settings and conduct

The present study will be performed in Afzalipour Hospital in Kerman. Hemodynamics (blood pressure, heart rate, arterial blood oxygen saturation and respiration rate) once before drug administration and once after drug injection before endoscopy and then every 5 minutes until completion of work through the patient monitoring system are checked and registered. The patient's tolerance should then be checked which is characterized by gagging or shaking hands. After the endoscopy, we check which group of drugs the patients wake up earlier. In order to blind one-way study, all data entry measures will be performed by a person unaware of the patient group.

Participants/Inclusion and exclusion criteria

Inclusion criteria include patients undergoing upper endoscopy aged 20 to 40 years.Exclusion criteria included patient addiction, hypertension, hyperlipidemia, thyroid disease and any other comorbidities, also contraindications to Lidocaine use, including patients with G6PD, myasthenia gravis, methemoglobinemia, heart block, and Wolff-Parkinson-White syndrome, Adams-Stokes syndrome and low blood potassium levels.

Intervention groups

All patients were given 0.05 mg / kg Midazolam and 40 mg / min Propofol and randomly given 1 ug / kg Fentanyl to the first group and 1.5 mg / kg intravenous Lidocaine to the second group 90 seconds before each procedure.

Main outcome variables

Reduction of blood pressure fluctuations, heart rate, respiration rate, etc. during upper endoscopy

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20101220005426N11**
Registration date: **2021-08-20, 1400/05/29**
Registration timing: **prospective**

Last update: **2021-08-20, 1400/05/29**
Update count: **0**

Registration date

2021-08-20, 1400/05/29

Registrant information

Name
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Anesthesiology department, Kerman University of Medical Sciences
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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-09-23, 1400/07/01

Expected recruitment end date

2022-03-20, 1400/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigation of hemodynamic effects of two combinations of Propofol-Fentanyl and Propofol-Lidocaine in patients undergoing upper endoscopy

Public title

Hemodynamic effects of Propofol-Fentanyl and Propofol-Lidocaine in patients undergoing endoscopy

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Patients undergoing upper endoscopy Patients aged 20 to 40 years

Exclusion criteria:

Addiction High blood pressure Hyperlipidemia Underlying disease, including thyroid disease, etc. Patients with G6PD disorder Myasthenia gravis methemoglobinemia Heart block Wolff-Parkinson-White syndrome Adams-Stokes syndrome Low blood potassium levels

Age

From **20 years** old to **40 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **198**

Randomization (investigator's opinion)

Randomized

Randomization description

To randomize people to the two groups, the block randomization method is used in such a way that 4 blocks are used. In each block of 4, 2 people are assigned to the first group and 2 people to the second group. R statistical software is used for random block allocation

Blinding (investigator's opinion)

Single blinded

Blinding description

In order to blind the one side of the study, all data recording measures will be performed by a person unaware of the patient group.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Kerman University of Medical Sciences

Street address

Vice chancellor for research, Kerman University of Medical Sciences, Jahad Blvd, Somayye Crossroads, Shariaati St, Kerman

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Province

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Postal code

7619813159

Approval date

2021-05-03, 1400/02/13

Ethics committee reference number

IR.KMU.REC.1400.104

Health conditions studied

1

Description of health condition studied

upper endoscopy

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Blood pressure

Timepoint

Checking of blood pressure once before drug administration and once after drug injection before endoscopy and then every 5 minutes until completion of work

Method of measurement

Patient monitoring system

2

Description

Heart rate

Timepoint

Checking of heart rate once before drug administration and once after drug injection before endoscopy and then every 5 minutes until completion of work

Method of measurement

Patient monitoring system

3

Description

Arterial blood oxygen saturation

Timepoint

Checking of arterial blood oxygen saturation once before drug administration and once after drug injection before endoscopy and then every 5 minutes until completion of work

Method of measurement

Patient monitoring system

4

Description

Respiratory rate

Timepoint

Checking of respiratory rate saturation once before drug administration and once after drug injection before endoscopy and then every 5 minutes until completion of work

Method of measurement

Patient monitoring system

5

Description

Gag reflex

Timepoint

During upper endoscopy

Method of measurement

Doctor checkup

Secondary outcomes

empty

Intervention groups

1

Description

The first intervention group: after receiving 0.05 mg / kg Midazolam and 40 mg / min Propofol maintenance, we give the first group 1 ug / kg Fentanyl (from Abu Reihan company) with the brand name of Fanijekt 90 seconds before each procedure.

Category

Rehabilitation

2

Description

Second intervention group: After receiving 0.05 mg / kg Midazolam and 40 mg / min Propofol maintenance, we give the second group 1.5 mg / kg intravenous Lidocaine 90 seconds before each procedure.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Bahonar Hospital, Kerman

Full name of responsible person

Mehdi Ahmadinejad

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Shahid Bahonar Hospital, Qarani St, Valiasr Crossroads, Shariaati St, Kerman

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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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

Kerman 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

Kerman University of Medical Sciences

Full name of responsible person
Mehdi Ahmadinejad
Position
Assistant Professor- Fellow of Intensive Care
Latest degree
Specialist
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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
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Undecided - It is not yet known if there will be 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