Clinical Trial Protocol
Iranian Registry of Clinical Trials

19 Sep 2026

A Clinical trial to Compare the effects of sedation with propofol protocol and midazolam and pethidine protocol on endoscopy's side effects in patients referring for endoscopy

Protocol summary

Summary

This study is Clinical trial to Compare the effects of sedation with propofol protocol and midazolam and pethidine protocol on endoscopy's side effects in patients referring for endoscopy in Ahwaz Imam Khomeini Hospital. The present study is a single-centered double blind randomized controlled trial. The study population includes patients who are referred to Imam Khomeini Hospital in Ahwaz for endoscopy. The main criteria for entering the study are age over 18 years; alertness; ability to participate in gastrointestinal tract endoscopy under sedimentation. The main criteria for exclusion from the study are lack of alertness and sensitivity to anesthetic drugs. The sample size is 266 and the time for intervention is from October to April. In this study, primary and secondary outcomes will be compared in patients undergoing endoscopy under anesthesia with propofol protocol (133 patients) and with midazolam and pethidine protocol (133 patients). Assignment of patients to the study groups will be done by random block method using six blocks. Standardized questionnaire will be used to collect demographic characteristics, laboratory data and clinical information of patients. The initial outcomes of the trial include duration of endoscopy, recovery time after endoscopy, and patient's satisfaction score after awakening and the secondary consequences of the trial include arrhythmia, hypoxia, hypotension, nausea and vomiting. The appropriate statistical tests will be use to compare data between the two intervention groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017070834959N1**
Registration date: **2017-11-09, 1396/08/18**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2017-11-09, 1396/08/18

Registrant information

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Recruitment status

Recruitment complete

Funding source

Vice-Chancellor for Research Affairs of Ahvaz Jundishapur University of Medical Sciences.

Expected recruitment start date

2017-09-23, 1396/07/01

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

A Clinical trial to Compare the effects of sedation with

propofol protocol and midazolam and pethidine protocol on endoscopy's side effects in patients referring for endoscopy

Public title
Comparison of the effects and side effects of sedation with propofol protocol and midazolam and pethidine protocol in endoscopic patients.
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria: Age above 18y/o; Consciousness; Ability to participate in the gastrointestinal tract endoscopy under sedation. Exclusion criteria: Non-consciousness; allergy to anesthetic drugs.
Age
From **18 years** old
Gender
Both

Phase
4
Groups that have been masked
No information
Sample size
Target sample size: **266**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Double 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 Ahvaz Jundishapur University of Medical Sciences
Street address
Golestan Blvd
City
Ahvaz
Postal code
Approval date
2017-06-03, 1396/03/13
Ethics committee reference number
IR.AJUMS.REC.1396.220

Health conditions studied

1

Description of health condition studied
Endoscopy under sedation by propofol
ICD-10 code
-
ICD-10 code description
-

2

Description of health condition studied
Endoscopy under sedation with midazolam and pethidine
ICD-10 code
-
ICD-10 code description
-

Primary outcomes

1

Description
Duration of the endoscopy
Timepoint
GI endoscopy—from start to finish
Method of measurement
Stopwatch

2

Description
Recovery time after endoscopy
Timepoint
After endoscopy
Method of measurement
Stopwatch

3

Description
Patient satisfaction after endoscopy
Timepoint
After endoscopy
Method of measurement
Score expressed by the patient

Secondary outcomes

1

Description
Hypoxia
Timepoint
Before intervention and after intervention
Method of measurement
Pulse oximetry

2

Description
Cardiac arrhythmia
Timepoint

Before intervention and after intervention
Method of measurement
Heart monitoring

3

Description
Blood pressure
Timepoint
Before and after intervention
Method of measurement
Sphygmomanometer

4

Description
Nausea
Timepoint
After intervention
Method of measurement
Observation

5

Description
Vomiting
Timepoint
After intervention
Method of measurement
Observation

Intervention groups

1

Description
Intervention group 1: Endoscopy of the patient under sedation with propofol protocol
Category
Treatment - Other

2

Description
Intervention group 2: Endoscopy of the patient under sedation with midazolam plus pethidine protocol
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Ahvaz Imam Khomeini Hospital
Full name of responsible person
Jalal Sayyah
Street address
Imam Khomeini Hospital of Ahvaz, Azadegan street
City
Ahvaz

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice-Chancellor for Research Affairs of Ahvaz Jundishapur University of Medical Sciences.
Full name of responsible person
Behzad Sharif Makhmalzadeh
Street address
Golestan Blvd
City
Ahvaz
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice-Chancellor for Research Affairs of Ahvaz Jundishapur University of Medical Sciences.
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

Contact
Name of organization / entity
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty