

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 Jul 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 sedation. 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 used 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

Name

Jalal Sayyah

Name of organization / entity

Ahwaz- Ahwaz Jundishapur University of Medical Sciences

Country

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Recruitment status

Recruitment complete

Funding source

Vice-Chancellor for Research Affairs of Ahwaz 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
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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
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
Ahvaz Jundishapur University of Medical Sciences
Full name of responsible person
Jalal Sayyah
Position
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Web page address**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

Person responsible for updating data**Contact****Name of organization / entity**

Ahvaz Jundishapur University of Medical Sciences

Full name of responsible person

Jalal Sayyah

Position

Fellowship of Gastroenterology/specialist resident

Other areas of specialty/work