

Clinical Trial Protocol

Iranian Registry of Clinical Trials

08 Jul 2026

Comparative study on the sedative effect of ketamine, magnesium sulfate and propofol in upper endoscopy

Protocol summary

Registration timing: **registered_while_recruiting**

Study aim

Comparative study on the sedative effect of ketamine, magnesium sulfate and propofol in upper endoscopy

Last update: **2020-02-06, 1398/11/17**

Update count: **0**

Design

Randomized clinical trial, with three arm parallel group of 201 patients, will be enrolled between January 2020 and August 2020.

Registration date

2020-02-06, 1398/11/17

Settings and conduct

In this research, 201 eligible patients need to perform endoscopy referring to Qom gastroenterology clinic will be selected. Then, patients by block randomization will be divided randomly into three interventions groups. The first intervention group will receive propofol and second intervention group will receive ketamine and the third group will receive ketamine and magnesium sulfate. Patients will not be aware of the type of intervention.

Registrant information

Name

Ahmad Hormati

Name of organization / entity

Qom university of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 25 3612 2053

Email address

hormatia@muq.ac.ir

Participants/Inclusion and exclusion criteria

Inclusion criteria: patients aged more than 12 years, need to perform endoscopy. Exclusion criteria: American Society of Anesthesiologists (ASA) score 3 or more, history of allergy to used drugs.

Recruitment status

Recruitment complete

Funding source

Intervention groups

Intervention group 1: Intravenous midazolam 0.03 mg/kg + Intravenous propofol 1 mg/kg, before endoscopy.

Intervention group 2: Intravenous midazolam 0.03 mg/kg + intravenous ketamine 0.5 mg/kg, before endoscopy.

Intervention group 3: Intravenous midazolam 0.03 mg/kg + intravenous ketamine 0.3 mg/kg + intravenous magnesium sulfate 2 gr, before endoscopy

Expected recruitment start date

2020-01-17, 1398/10/27

Expected recruitment end date

2020-07-17, 1399/04/27

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Main outcome variables

Physician's and patient's satisfaction

General information

Scientific title

Comparative study on the sedative effect of ketamine, magnesium sulfate and propofol in upper endoscopy

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20161205031252N12**

Registration date: **2020-02-06, 1398/11/17**

Public title

Comparative study on the sedative effect of ketamine, magnesium sulfate and propofol in endoscopy

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients aged more than 12 years

Exclusion criteria:

History of allergy to medications ASA physical status classification system more than 3

Age

From 12 years old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size

Target sample size: 201

Randomization (investigator's opinion)

Randomized

Randomization description

The patients will be assigned to three groups of interventions by block randomization. For this purpose blocks of size 6 will be used. 34 blocks will include. To hide the random allocation, the numbered dark envelopes will be used, in which the group name is specified in the random sequence generated. Then, according to the order of entering samples, for the first patient the envelope number one is opened and the group will be identified until the end

Blinding (investigator's opinion)

Double blinded

Blinding description

Participants and endoscopist does not know the allocation and drugs are injected into the patient by an anesthesiologist.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Qom University of Medical Sciences

Street address

No. 83, 4th alley, 1.1 alley, Safashahr Blvd

City

Qom

Province

Ghoum

Postal code

3716987366

Approval date

2019-11-05, 1398/08/14

Ethics committee reference number

IR.MUQ.REC.1398.103

Health conditions studied

1

Description of health condition studied

Diseases of upper digestive system which need endoscopy

ICD-10 code

K25

ICD-10 code description

Gastric ulcer

2

Description of health condition studied

Diseases of upper digestive system which need endoscopy

ICD-10 code

K22.7

ICD-10 code description

Barrett's esophagus

Primary outcomes

1

Description

Physician's satisfaction of the adequacy of sedation for performing endoscopy

Timepoint

Immediately after completing the endoscopy

Method of measurement

Comfort score

2

Description

Patient's satisfaction of the adequacy of sedation for performing endoscopy

Timepoint

Immediately after completing the endoscopy

Method of measurement

Comfort score

3

Description

Sedation response score

Timepoint

Immediately after completing the endoscopy

Method of measurement

Ramsay sedation scale

Secondary outcomes

1

Description

Recovery time

Timepoint

At the time of leaving recovery

Method of measurement

Time recording

Intervention groups

1

Description

Control group: Amp midazolam, Daroopaksh, 0.03 mg/kg, once, intravenous, before endoscopy + Amp propofol, Daroopaksh, 1 mg/kg, once, intravenous, before endoscopy

Category

Treatment - Drugs

2

Description

Intervention group 1: Amp midazolam, Daroopaksh, 0.03 mg/kg, once, intravenous, before endoscopy + Amp ketamine, Daroopaksh, 0.5 mg/kg, once, intravenous, before endoscopy

Category

Treatment - Drugs

3

Description

Intervention group 2: Amp midazolam, Daroopaksh, 0.03 mg/kg once, intravenous, before endoscopy + Amp ketamine, Daroopaksh, 0.3 mg/kg once, intravenous, before endoscopy + Amp magnesium sulfate, Daroopaksh, 2 gr, once, intravenous, before endoscopy

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Beheshti Hosbital

Full name of responsible person

Ahmad Hormati

Street address

Shahid Beheshti Hospital, Shahid Beheshti Blvd, Azadegan Square.

City

Qom

Province

Ghous

Postal code

3719964797

Phone

+98 25 3612 2824

Email

hormatia@muq.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ghous University of Medical Sciences

Full name of responsible person

Hossein Saghafi

Street address

Gastroenterology and Hepatology Disease Research Center, Shahid Beheshti Hospital, Shahid Beheshti Blvd, Azadegan Squ

City

Qom

Province

Ghous

Postal code

3719964797

Phone

+98 25 3612 2824

Email

hormatia@muq.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Ghous 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

Ghous University of Medical Sciences

Full name of responsible person

Ahmad Hormati

Position

Assistant Professor of adults Gastroenterology and hepatology

Latest degree

Subspecialist

Other areas of specialty/work

Internal Medicine

Street address

Gastroenterology and Hepatology Disease Research Center, Endoscopy Unit, Shahid Beheshti Hospital, Shahid Beheshti Blv, Qom

City

Qom

Province

Ghous

Postal code

3719964797

Phone

+98 25 3612 2053

Fax

+98 25 3612 2053

Email

Hormatia@muq.ac.ir

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Ghous University of Medical Sciences

Full name of responsible person

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Postal code

3719964797

Phone

+98 25 3612 2053

Fax

+98 25 3612 2053

Email

hormatia@yahoo.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Ghous University of Medical Sciences

Full name of responsible person

Dr Ahmad Hormati

Position

Assistant Professor of Gastroenterology

Latest degree

Subspecialist

Other areas of specialty/work

Internal Medicine

Street address

Gastroenterology and Hepatology Disease Research Center, Shahid Beheshti Hospital, Qom

City

Qom

Province

Ghous

Postal code

3719964794

Phone

+98 25 3612 2053

Fax

+98 25 3612 2053

Email

hormatia@yahoo.com

Web page address

<http://qddrc.muq.ac.ir/index.aspx>

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

The data are specific to this study

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