

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 Jun 2026

Investigation and comparison of sedative effects of ketofol and midazolam-ketamine combination in endoscopy of upper gastrointestinal tract in children 1 to 14 years

Protocol summary

Study aim

Investigation and comparison of sedative effects of ketofol and midazolam-ketamine combination in endoscopy of upper gastrointestinal tract in children 1 to 14 years

Design

In this interventional study, 54 patients who met the inclusion criteria were selected and divided into two groups using block randomization method (n=27 in each group). Proper counseling were done and a written informed consent were obtained before starting the treatment regimen.

Settings and conduct

The present study was performed on 54 children aged 1 to 14 years who referred to the pediatric gastroenterology center of Taleghani Hospital in Gorgan in 2014. The first group received ketamine 1 mg / kg and 1 mg / kg propofol and the second group received 0.5 mg / kg midazolam and 2 mg / kg ketamine intravenously and by slow injection. Systolic, diastolic blood pressure and heart rate were measured before and after 5, 10, 30, and 60 minutes after sedation.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Candidate for endoscopy, age 1 to 14 years old. Exclusion criteria: Cardiopulmonary disease

Intervention groups

Intervention group: Use of 1 mg /kg ketamine (Pfizer Co. Germany) and 1 mg /kg propofol (Tehranchemie Co. product) . Control group: Use of 0.05 mg / kg midazolam (Caspian Tamin Co. Iran) and 2 mg /kg ketamine (Pfizer Co. Germany) .

Main outcome variables

Systolic and diastolic blood pressure

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200620047853N1**
Registration date: **2020-06-22, 1399/04/02**
Registration timing: **retrospective**

Last update: **2020-06-22, 1399/04/02**

Update count: **0**

Registration date

2020-06-22, 1399/04/02

Registrant information

Name

Vahid Adiban

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 45 3325 1410

Email address

v.adiban@arums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2014-08-23, 1393/06/01

Expected recruitment end date

2014-12-22, 1393/10/01

Actual recruitment start date

2014-08-23, 1393/06/01

Actual recruitment end date

2014-12-22, 1393/10/01

Trial completion date

2014-12-22, 1393/10/01

Scientific title

Investigation and comparison of sedative effects of

ketofol and midazolam-ketamine combination in endoscopy of upper gastrointestinal tract in children 1 to 14 years

Public title

Investigation and comparison of sedative effects of ketofol and midazolam-ketamine combination in endoscopy

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Candidate for endoscopy Age 1 to 14 years old

Exclusion criteria:

Cardiopulmonary disease

Age

From **1 year** old to **14 years** old

Gender

Both

Phase

1-2

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **54**

Actual sample size reached: **54**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients randomly were assigned to one of two identified groups through blockade.

Blinding (investigator's opinion)

Double blinded

Blinding description

Patients and the physician who examined the patients did not be aware of the intervention.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethical Committee Golestan University of Medical Sciences

Street address

Golestan University of Medical Sciences, Shastkola, Gorgan

City

Gorgan

Province

Golestan

Postal code

4934174515

Approval date

2013-11-17, 1392/08/26

Ethics committee reference number

237192082602

Health conditions studied

1

Description of health condition studied

Endoscopy

ICD-10 code

Y61.4

ICD-10 code description

During endoscopic examination

Primary outcomes

1

Description

Systolic blood pressure

Timepoint

Before and 5, 10, 30 and 60 minutes after sedation

Method of measurement

Barometer

2

Description

Diastolic blood pressure

Timepoint

Before and 5, 10, 30 and 60 minutes after sedation

Method of measurement

Barometer

Secondary outcomes

1

Description

Heart rate

Timepoint

Before and 5, 10, 30 and 60 minutes after sedation

Method of measurement

Heart rate count

Intervention groups

1

Description

Intervention group: Use of 1 mg /kg ketamine and 1 mg /kg propofol

Category

Treatment - Drugs

2

Description

Control group: Use of 0.05 mg / kg midazolam and 2 mg / kg ketamine at

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Taleghani Hospital

Full name of responsible person

Vahid Adiban

Street address

Taleghani Hospital, Janbazan Blvd, Gorgan

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Gorgan University of Medical Sciences

Full name of responsible person

Masood Khoshnia

Street address

Deputy of Research & Technology, Golestan University of Medical Sciences, Shastcola, Gorgan

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drkhniya@goums.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Gorgan 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

Ardabil University of Medical Sciences

Full name of responsible person

Vahid Adiban

Position

Assistant professor

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

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Person responsible for updating data

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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