

# 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

##### City

Gorgan

##### Province

Golestan

##### Postal code

4916668197

##### Phone

+98 17 3222 7720

##### Email

v.adiban@arums.ac.ir

## 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

##### City

Gorgan

##### Province

Golestan

##### Postal code

4934174515

##### Phone

+98 17 3245 2651

##### Email

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

##### Street address

Imam Khomeini Hospital, Shahid Jeddi Street, Ardabil

##### City

Ardabil

##### Province

Ardabil

##### Postal code

5618985991

##### Phone

+98 45 3325 1401

##### Email

v.adiban@arums.ac.ir

## Person responsible for scientific 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

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## Person responsible for updating data

### Contact

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Ardabil University of Medical Sciences

**Full name of responsible person**

Vahid Adiban

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**Province**

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**Postal code**

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**Phone**

+98 45 3325 1401

**Email**

v.adiban@arums.ac.ir

## 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