Clinical Trial Protocol
Iranian Registry of Clinical Trials

30 May 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
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 updating data

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
۵۶۱۸۹-۸۵۹۹۱

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