

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

The comparison assessment the sedative effect of ketamine and propofol with oral midazolam in pediatric upper gastrointestinal endoscopy

Protocol summary

Summary

In order to compare the sedative effect of ketamine and propofol with oral midazolam during upper gastrointestinal endoscopy 94 children 1-14 years old with gastrointestinal disease and classification 1 and 2 ASA(American Society of Anesthesiologists) with chronic disease, cardiovascular and do not use effective drugs on the cardiovascular system and nervous system;during 6 months observing and studying in two groups of oral midazolam with ketamine and oral midazolam with propofol.record certain vital signs (heart rate, respiratory rate, mean arterial pressure, oxygen saturation) at different times, the need for additional doses of the drug and level of sedation effect of both regime.The results obtained during upper gastrointestinal endoscopy compared to sedative drug regimens will be studied.

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Recruitment status

Recruitment complete

Funding source

Babol University of Medical Sciences

Expected recruitment start date

2016-11-10, 1395/08/20

Expected recruitment end date

2017-05-10, 1396/02/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016121831457N1**

Registration date: **2017-02-15, 1395/11/27**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2017-02-15, 1395/11/27

Registrant information

Name

Mahdi Farhadi

Name of organization / entity

Babol University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

Scientific title

The comparison assessment the sedative effect of ketamine and propofol with oral midazolam in pediatric upper gastrointestinal endoscopy

Public title

The comparison assessment the sedative effect of ketamine and propofol with oral midazolam in pediatric upper gastrointestinal endoscopy

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion Criteria:1-14 years old childs with gastrointestinal disease ; children with grade I, II classification (American Society of Anesthesia) ASA
Exclusion Criteria: chronic diseases such as cardio-pulmonary disease, diabetes, infectious diseases and oncology ; chronic use of drugs affecting the respiratory system and cardiovascular, CNS

Age

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

Gender

Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **94**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Single blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Babol University of Medical Sciences

Street address

Vice- Chancellor for Research Technology Affairs,
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Approval date

2016-11-09, 1395/08/19

Ethics committee reference number

MUBABOL.HRI.REC.1395.45

Health conditions studied

1

Description of health condition studied

sedation effect of drug regimen in gasterointestinal
endoscopy

ICD-10 code

R10

ICD-10 code description

Abdominal and pelvic pain

2

Description of health condition studied

sedation effect of drug regimen in gasterointestinal
endoscopy

ICD-10 code

R11

ICD-10 code description

Nausea and vomiting

3

Description of health condition studied

sedation effect of drug regimen in gasterointestinal
endoscopy

ICD-10 code

R12

ICD-10 code description

Heartburn

4

Description of health condition studied

sedation effect of drug regimen in gasterointestinal
endoscopy

ICD-10 code

R13

ICD-10 code description

Dysphagia

5

Description of health condition studied

sedation effect of drug regimen in gasterointestinal
endoscopy

ICD-10 code

R19

ICD-10 code description

Other symptoms and signs involving the digestive
system and abdomen

Primary outcomes

1

Description

check the heart rate after administration of oral
midazolam and ketamine and propofol sedative drugs

Timepoint

1)Two minutes after administration of oral midazolam 2)
When entering the endoscope 3) five minutes after
endoscopic

Method of measurement

vital sign monitoring machine(saadat,BS-SN SNTI/e2/m/c)

2

Description

check the Respiratory Rate after administration of oral
midazolam and ketamine and propofol sedative drugs

Timepoint

1)Two minutes after administration of oral midazolam 2)
When entering the endoscope 3) five minutes after
endoscopic

Method of measurement

vital sign monitoring machine(saadat,BS-SN SNTI/e2/m/c)

3

Description

The possible need to add a dose of medication in MP groups as inadequate sedation with commonly defined doses

Timepoint

during endoscopy if inadequate sedation

Method of measurement

The milligrams of the drug

4

Description

The sedative effect in both groups before and during endoscopy start

Timepoint

Begins immediately before and five minutes after the start of endoscopy

Method of measurement

Rasey score clasification($5 \leq \text{RSS}$)

5

Description

check the Mean Arterial Pressure after administration of oral midazolam and ketamine and propofol sedative drugs

Timepoint

1)Two minutes after administration of oral midazolam 2) When entering the endoscope 3) five minutes after endoscopic

Method of measurement

vital sign monitoring machine(saadat,BS-SN SNTI/e2/m/c)

6

Description

check the arterial O2 saturation after administration of oral midazolam and ketamine and propofol sedative drugs

Timepoint

1)Two minutes after administration of oral midazolam 2) When entering the endoscope 3) five minutes after endoscopic

Method of measurement

vital sign monitoring machine(saadat,BS-SN SNTI/e2/m/c)

7

Description

The possible need to add a dose of medication in MK groups as inadequate sedation with commonly defined doses

Timepoint

during endoscopy if inadequate sedation

Method of measurement

The milligrams of the drug

Secondary outcomes

1

Description

Compare vital signs after endoscopy

Timepoint

Fifteen minutes after the completion of endoscopy

Method of measurement

vital sign monitorin mashine(saadat)

2

Description

The endoscopist satisfaction of sedation effect of each drug regimen

Timepoint

After the endoscopy

Method of measurement

Skills and experience of the endoscopist

3

Description

Compare potential drug side effects in both groups.

Timepoint

After drug administration, during endoscopy,finish endoscopğ

Method of measurement

Phisical exam and History

4

Description

compare of recovery score

Timepoint

Fifteen minutes after the completion of endoscopy

Method of measurement

steward score system

Intervention groups

1

Description

In MP group oral midazolam half-mg dose and a maximum of 20 milligrams per kilogram of body weight

Category

Treatment - Other

2

Description

Patients in the MP group injected with Propofol (Dayateb co.IRof Iran Manufactured by Claris) bolus dose2 mg / kg (children younger than 3 years) and 1 mg / kg (in children older than 3 years) are to $5 \leq$ (RSS) arrive and then propofol infusion at a dose of 100μ / kg / min maintenance dose for sedation begins

Category

Other

3

Description

MK Group IV sedation with ketamine in slow (Trittan / Germany) bolus 1-2 mg / kg starts and after about 15-10 minutes the effect of ketamine sedation was reduced by as much as 0/5-1 mg / kg in during the procedure is repeated

Category

Other

4

Description

In MK group oral midazolam half-mg dose and a maximum of 20 milligrams per kilogram of body weight

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Shafizade Pediatric Hospital

Full name of responsible person

Dr Mohammadreza Esmaeili Dooki

Street address

Children's Hospital, Amirkola, Babol, Mazandaran Province 4731741151, IR Iran. Tel: 00981132354951 Fax: 00981132340656 Phone Num: 00989111112284 esmaeilidooki@yahoo.com

City

Babol , Amirkola

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Babol University of Medical Sciences

Full name of responsible person

Dr Aliakbar Moghadamnia

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City

Babol

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Babol 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

Amirkola Childeren's Hospital

Full name of responsible person

Dr Mahdi Farhadi

Position

Peditric's Assistant

Other areas of specialty/work

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Person responsible for scientific inquiries

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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