

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 Jul 2026

The comparison assessment of sedative effect of intravenous ktamine and midazolam versus oral combination of midazolam and ketamin for dagnostic upper gastrointestinal endoscopy in children

Protocol summary

Study aim

The comparison assessment of sedative effect of intravenous ketamine and midazolam versus oral combination of midazolam and ketamin for diagnostic upper gastrointestinal endoscopy in children

Design

Randomized clinical trial with parallel groups. 100 patients have randomly divided into intervention groups A and B with a table of random numbers and Randomizer software.

Settings and conduct

The population of this study was aged 3-16 years old who referred to Children's Hospital Decedent Shafi'zadeh Amirkola in Babol. Patients are randomly divided into two Intervention groups with a table of random numbers by computer.

Participants/Inclusion and exclusion criteria

Inclusion criteria: patients have not underlying problem, age 3 -16 years old. Exclusion criteria: respiratory, heart, kidney or liver diseases; apparent neurological inability; hypersensitivity to Benzodiazepines.

Intervention groups

Intervention group 1: Oral Midazolam (Exir Company) 0.5 mg / kg with a maximum dose of 20 mg and intramuscular Ketamine (Tritau Company) with a dose of 0.5 mg / kg. Intervention group 2: Oral Midazolam (Exir Company) 0.5 mg / kg with a maximum dose of 20 mg and oral ketamine (Tritau Company) with a dose of 5 mg / kg up to a maximum of 70 mg.

Main outcome variables

Sedation

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190529043750N2**

Registration date: **2020-05-14, 1399/02/25**

Registration timing: **registered_while_recruiting**

Last update: **2020-05-14, 1399/02/25**

Update count: **0**

Registration date

2020-05-14, 1399/02/25

Registrant information

Name

mohammad esmaeili

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 11 3233 8305

Email address

dresmaeili48@mubabol.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-01-20, 1398/10/30

Expected recruitment end date

2021-01-19, 1399/10/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The comparison assessment of sedative effect of intravenous ktamine and midazolam versus oral combination of midazolam and ketamin for dagnostic

upper gastrointestinal endoscopy in children

Public title
Sedative effect for diagnostic upper gastrointestinal endoscopy in children

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Patients have not underlying problem Age 3 -16 years old
Exclusion criteria:
Respiratory diseases Heart diseases Kidney diseases
Liver diseases Apparent neurological inability
Hypersensitivity to benzodiazepines

Age
From **3 years** old to **16 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **100**

Randomization (investigator's opinion)
Randomized

Randomization description
Patients are randomly divided into three groups A and B with a table of random numbers (a random number table is a collection of numbers that are generated without a specific pattern or order and completely randomized. The participants allocation sequence in two groups performed with a Randomizer software.

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Babol University Of Medical Sciences

Street address

Daneshgah Square, Ganjafrooz Avenue

City

Babol

Province

Mazandaran

Postal code

47176-41367

Approval date

2020-01-19, 1398/10/29

Ethics committee reference number

IR.MUBABOL.HRI.REC.1398.329

Health conditions studied

1

Description of health condition studied

Sedation in endoscopy

ICD-10 code

Y60.4

ICD-10 code description

During endoscopic examination

Primary outcomes

1

Description

Sedation

Timepoint

During and 1 hour after endoscopy

Method of measurement

Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group 1: Oral Midazolam (Exir Company) 0.5 mg / kg with a maximum dose of 20 mg and intramuscular Ketamine (Tritau Company) with a dose of 0.5 mg / kg

Category

Treatment - Drugs

2

Description

Intervention group 2: Oral Midazolam (Exir Company) 0.5 mg / kg with a maximum dose of 20 mg and oral ketamine (Tritau Company) with a dose of 5 mg / kg up to a maximum of 70 mg

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Children's Hospital Decedent Shafi'zadeh Amirkola

Full name of responsible person

Mohammad Esmaeili

Street address

Babol-Amirkola-Children's Hospital Decedent
Shafi'zadeh Amirkola

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dresmaeili48@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Babol University of Medical Sciences

Full name of responsible person

Reza Ghadimi

Street address

Vice-chancellor Of Research, Daneshgah Square,
Ganjafrooz Avenue

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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

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

Babol University of Medical Sciences

Full name of responsible person

Ali Omrani-Rad

Position

Student

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

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Ayatollah Rouhani Hospital, Daneshgah Square,
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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

Mohammad Esmaeili

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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Full name of responsible person

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Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

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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

There is still no plan for its publish.

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