Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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
City
Babol
Province
Mazandaran
Postal code
4731-741151
Phone
+98 11 3235 4951
Email
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
City
Babol
Province
Mazandaran
Postal code
47176-41367
Phone
+98 11 3219 7667
Email
rezaghadimi@yahoo.com
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
Street address
Ayatollah Rouhani Hospital, Daneshgah Square, Ganjafrooz Avenue
City
Babol
Province
Mazandaran
Postal code
47176-41367
Phone
+98113238301
Email
Omraniradali@gmail.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Babol University of Medical Sciences
Full name of responsible person
Mohammad Esmaeili
Position
Assistant Professor
Latest degree
Specialist
Other areas of specialty/work
Anesthesiology
Street address
Ayatollah Rouhani Hospital, Daneshgah Square, Ganjafrooz Avenue
City
Babol
Province
Mazandaran
Postal code
47176-41367
Phone
+98 11 3233 8301
Email
dresmaeili48@yahoo.com

Person responsible for updating data

Contact
Name of organization / entity
Babol University of Medical Sciences
Full name of responsible person
Mohammad Esmaeili
Position
Assistant Professor
Latest degree
Specialist
Other areas of specialty/work
Anesthesiology

Street address
Ayatollah Rouhani Hospital, Daneshgah Square, Ganjafrooz Avenue
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Babol
Province
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Postal code
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Email
dresmaeili48@yahoo.com

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