

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Comparison of the sedation effect of oral Ketamine and intranasal Midazolam in children undergoing upper endoscopy at Rasht 17 Shahrivar hospital

Protocol summary

Summary

This is a randomized double blind clinical trial study that perform on 100 children between the ages of 2 to 14 years old at 17 Shahrivar Hospital, Rasht, Iran in 2014, undergoing upper endoscopy according to gastroenterologist diagnosis. After obtaining written consent from their parents, the patients are divided into two groups (ketamine or midazolam) using random fixed block method. In the group Ketamin, 30 minutes prior to the endoscopy, 5 mg/kg of ketamine dissolved in 0.5 cc/kg of usp syrup (mixture of sucrose and water in a ratio of 85%) will be given to all children and normal saline as placebo will be dropped into the nose. In the midazolam group, 0.1 mg/kg administrate intranasal and the placebo usp syrup is fed. In all children, age, sex, soothe, calm, fear, cooperation and children behavior at separation time from their parents, the arterial oxygen saturation, blood pressure, pulse rate and respiratory rate before, during and after endoscopy and complications such as nausea, vomiting, seizures, Laryngospasm and duration of sedation and amnesia or remembrance of procedure to be reviewed. After collecting the data, they will be entered into SPSS version 17. For analyzing, T test for quantitative variables and Chi square test for qualitative variables will be used.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014111419936N1**

Registration date: **2014-12-12, 1393/09/21**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2014-12-12, 1393/09/21

Registrant information

Name

Shohreh Maleknejad

Name of organization / entity

Guilan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 13 3332 6101

Email address

maleknejad@gums.ac.ir

Recruitment status

Recruitment complete

Funding source

The deputy of research, Guilan University of Medical Sciences

Expected recruitment start date

2014-12-22, 1393/10/01

Expected recruitment end date

2015-06-22, 1394/04/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the sedation effect of oral Ketamine and intranasal Midazolam in children undergoing upper endoscopy at Rasht 17 Shahrivar hospital

Public title

Comparison of the sedation effect of oral Ketamine and intranasal Midazolam in children undergoing upper

endoscopy

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: children who need endoscopy according to the pediatric gastroenterologist diagnosis. Patients should have not underlying problem and their age should be between of 2 and 14 years old. Exclusion criteria: patients with respiratory, heart, kidney and liver diseases and the apparent neurological inability or hypersensitivity to benzodiazepines and ketamine; no parental consent to sedate their patients; if an endoscopy complication occurs, such as bleeding and gastrointestinal endoscopy take too long.

Age

From **2 years** old to **14 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

The deputy of research of Guilan university of medical sciences

Street address

Gaz square-Rasht-Guilan

City

Rasht

Postal code

Approval date

2014-09-16, 1393/06/25

Ethics committee reference number

1930309905

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 and ramasy scale

Secondary outcomes

empty

Intervention groups

1

Description

In the group Ketamin, 30 minutes prior to the endoscopy, 5 mg/kg of ketamine dissolved in 0.5 cc/kg of usp syrup (mixture of sucrose and water in a ratio of 85%) will be given to all children and normal saline as placebo will be dropped into the nose.

Category

Treatment - Drugs

2

Description

In the midazolam group, 0.1 mg/kg administrate intranasal and the placebo usp syrup is fed.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

17 Shahrivar Hospital

Full name of responsible person

Dr. Shohreh Maleknejad

Street address

Namjoo street-Gaz square- Rasht-Guilan

City

Rasht

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

The deputy of research of Guilan University of Medical Sciences

Full name of responsible person

Dr. Abtin Heidarzadeh

Street address

Gaz square-Rasht-Guilan

City

Rasht

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

The deputy of research of Guilan 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**

Guilan University of Medical Sciences

Full name of responsible person

Dr. Shohre Maleknejad

Position

Pediatric gastroenterologist, assistant professor

Other areas of specialty/work**Street address**

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Web page address

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