

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 Jul 2026

Intranasal midazolam efficacy in upper endoscopy

Protocol summary

Ahvaz University of Medical Sciences and Health Services

Summary

Overall 105 patients who are candidate for upper endoscopy included and divided randomly to two groups: 53 people as group A (placebo) and 52 person as group B (midazolam). In group A 5CC water and in group B, 5mg midazolam diluted in equal volume of distilled water sprayed intranasal. After 45 minutes, upper endoscopy was done under monitoring and according check list duration, gag reflex, pulse rate, SPO2, amnesia and satisfaction was recorded and the DATA of two groups would be compared.

Expected recruitment start date

2010-10-10, 1389/07/18

Expected recruitment end date

2011-04-10, 1390/01/21

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

General information

Scientific title

Intranasal midazolam efficacy in upper endoscopy

Acronym

Public title

Midazolam sedation in endoscopy

IRCT registration information

IRCT registration number: **IRCT201110087740N1**

Registration date: **2013-04-22, 1392/02/02**

Registration timing: **retrospective**

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criterion: patients aged between 20 to 60 years old candidate for upper endoscopy. Exclusion criteria: GIB; COPD; CHF and intolerance to upper endoscopy.

Last update:

Update count: **0**

Registration date

2013-04-22, 1392/02/02

Age

From **20 years** old to **60 years** old

Registrant information

Name

Ahmad kadkhodae

Name of organization / entity

Ahwaz jondyshapur univercity

Country

Iran (Islamic Republic of)

Phone

+98 61 1373 1417

Email address

kadkhodae-a@ajums.ac.ir

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **105**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Recruitment status

Recruitment complete

Funding source

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ahvaz University of Medical sciences and Health Services of Ethic commite

Street address

Ahvaz University of Medical Sciences and Health services

City

Ahvaz

Postal code**Approval date**

2011-05-30, 1390/03/09

Ethics committee reference number

اچ تی ای-231

Health conditions studied**1****Description of health condition studied**

Upper endoscopy

ICD-10 code

K31-9

ICD-10 code description

Upper endoscopy for evaluation of upper GI diseases

Primary outcomes**1****Description**

Midazolam sedation for making upper endoscopy more comfort

Timepoint

2 hours after intervention

Method of measurement

Questionnaire

Secondary outcomes**1****Description**

Amnesia after endoscopy

Timepoint

2 hours after endoscoy

Method of measurement

Questionnaire

Intervention groups**1****Description**

Intranasal midazolam 1mg in intervention group and pure water in control.

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Endoscopy ward, Emam hospital

Full name of responsible person

Kadkhodae

Street address

Ahvaz Emam hospital

City

Ahvaz

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Ahvaz University of Medical Sciences and Health Services

Full name of responsible person

Ali Mard

Street address

Ahvaz- Kooye Ostadan

City

Ahvaz

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

Yes

Title of funding source

Ahvaz University of Medical Sciences and Health Services

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

Ahvaz University of Medical Sciences and Health Services

Full name of responsible person

Hajiani Eskandar

Position

Gastroenterologist

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

Number 1, Kkianpars, Ahvaz

City

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Position

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Person responsible for scientific inquiries

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Gastroenterologist

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Fax

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