Clinical Trial Protocol
Iranian Registry of Clinical Trials

24 Jun 2026

Comparing the effectiveness of intravenous and sublingual administration of midazolam for sedation of patients candidates for upper gastrointestinal endoscopy

Protocol summary

Study aim

Determining and comparing the effectiveness of intravenous and sublingual administration of midazolam for sedation in patients who are candidates for upper gastrointestinal endoscopy.

Design

Clinical trial with control group, with parallel groups, double-blind, randomized, phase 2 on 66 patients. Random allocation software version 1.0 under Windows is used for randomization.

Settings and conduct

This study is conducted on patients who were admitted for endoscopy in the endoscopy department of Shahid Sadoughi Hospital in Yazd. Before endoscopy, drugs are given to the patient and then the level of sedation is evaluated. Also, after the endoscopy, the patient is evaluated in terms of pain/discomfort and satisfaction. This study is double-blind, and neither the researcher nor the patient knows the type of drug prescribed, so the drugs are coded in two identical packages, and the third person gives the drug to the patient based on the specified code.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Adult patients who are candidates for upper gastrointestinal endoscopy who undergo diagnostic endoscopy for the first time. Non-inclusion criteria: Existence of moderate or severe systemic disease; History of taking sedatives and anti-anxiety drugs; Addiction to opioids, sedatives or psychotropic drugs; dissatisfaction to participate in the study

Intervention groups

Intervention group1: Before the procedure, patients are given 2.5 mg of intravenous midazolam and 1 ml of normal saline sublingually. Intervention group 2: Patients are given one milliliter of normal intravenous saline and 5 mg of midazolam sublingually before the procedure.

Main outcome variables

Sedation score, Pain/Discomfort score, Satisfaction score

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20100102002963N36**
Registration date: **2022-09-13, 1401/06/22**
Registration timing: **prospective**

Last update: **2022-09-13, 1401/06/22**
Update count: **0**

Registration date

2022-09-13, 1401/06/22

Registrant information

Name
Shekoufeh Behdad
Name of organization / entity
Shahid Sadoughi University of Medical Sciences
Country
Iran (Islamic Republic of)
Phone
+98 35 1822 1386
Email address
drbehdad@ssu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-09-23, 1401/07/01

Expected recruitment end date

2022-12-22, 1401/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing the effectiveness of intravenous and sublingual administration of midazolam for sedation of patients candidates for upper gastrointestinal endoscopy

Public title

Comparing the effectiveness of intravenous and sublingual administration of midazolam for sedation of patients who are candidates for upper gastrointestinal endoscopy.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Adult patients who are candidates for upper gastrointestinal endoscopy who undergo diagnostic endoscopy for the first time

Exclusion criteria:

Existence of moderate to severe systemic disease history of using of sedative or tranquilizer drugs addiction to opioids or any sedative or psychotropic drugs disagreement for cooperation in this study

Age

From **15 years** old to **55 years** old

Gender

Both

Phase

2

Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

The patients are randomly divided into two groups of 40 people in such a way that using the Random allocation software version 1.0 under Windows, we generate a random sequence using a simple random allocation method. In this table, numbers from 1 to 80 are specified and each number is assigned to an intervention group (A or B). Number 1 is assigned to the first qualified person, second person is number 2, and so on up to 80 patients. becomes Then based on the random allocation list prepared and by the software, it is determined which group A or B each person is placed in. All patients receive drugs and placebo (normal saline) both intravenously and sublingually. Each drug is placed in a package and the packages are coded and based on the table of random numbers and specified code, the drug and placebo are given to the patients by a third person who is not involved in evaluating the patients and recording the results.

Blinding (investigator's opinion)

Double blinded

Blinding description

The patients themselves and the researcher are not aware of the dose and method in which the patient received the drug, as all patients receive the drug and placebo (normal saline) both intravenously and sublingually. They do not know in which method the drug and which placebo is prescribed for each patient. Each drug is placed in a package and the packages are coded, and based on the table of random numbers and specified code, the drug is given to the patients by a third person who is not involved in evaluating the patients and recording the results.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Shahid Sadoughi University of Medical Sciences

Street address

Central building of Yazd University of Medical Sciences, Bahonar Square

City

Yazd

Province

Yazd

Postal code

8915887857

Approval date

2018-12-26, 1397/10/05

Ethics committee reference number

IR.SSU.MEDICINE.REC.1397.185

Health conditions studied

1

Description of health condition studied

The effect of medicine on the level of sedation, pain and discomfort and satisfaction of patients who are candidates for upper gastrointestinal endoscopy

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

The level of sedation

Timepoint
Before endoscopy
Method of measurement
A sedation score from 1 to 6 is given to each patient. In this way, score 1: the patient is awake, anxious and restless. Score 2: The patient is awake, alert, calm and cooperative. Score 3: The patient is awake and obeys orders. Score 4: The patient is asleep and responds quickly to stimulation (gentle blow to the forehead or loud sound stimulation). Score 5: The patient is asleep and gives a weak response to stimulation (gentle blow to the forehead area or loud sound stimuli). Score 6: The patient is asleep and does not respond to stimulation (gentle blow to the forehead area) or loud sound.

Secondary outcomes

1

Description
The level of Pain/discomfort
Timepoint
Before endoscopy
Method of measurement
Pain/discomfort Score(0-10)

2

Description
The level of satisfaction that gave a score of 1 to 10 for each patient.
Timepoint
Before endoscopy
Method of measurement
Satisfaction Score(0-10)

Intervention groups

1

Description
Intervention group: Before the procedure, patients are given 2.5 mg of intravenous midazolam and 1 ml of normal saline sublingually
Category
Treatment - Drugs

2

Description
Intervention group: Patients are given one milliliter of normal intravenous saline and 5 mg of midazolam sublingually before the procedure.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Shahid Sadoughi Hospital, Yazd
Full name of responsible person
Dr. Shekoufeh Behdad
Street address
Shahid Sadoughi Hospital, Ebnesina Blv, Safayieh, Yazd
City
Yazd
Province
Yazd
Postal code
8915887857
Phone
+98 35 3822 4101
Fax
+98 35 3822 7304
Email
sadoghi-hospital@ssu.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Yazd University of Medical Sciences
Full name of responsible person
Dr. Alireza Moradi
Street address
Central building of Yazd University of Medical Sciences, Bahonar Square
City
Yazd
Province
Yazd
Postal code
8915887857
Phone
+98 35 3149 2248
Email
alirezampr@gmail.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Yazd 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
Yazd University of Medical Sciences

Full name of responsible person
Dr. Shekoufeh Behdad

Position
professor of Shahid Sadoughi University of Medical Sciences, Yazd

Latest degree
Specialist

Other areas of specialty/work
Anesthesiology

Street address
Shahid Sadoughi Hospital, Ebnesina Blv, Safayieh, Yazd

City
Yazd

Province
Yazd

Postal code
8915887857

Phone
+98 35 3823 1932

Email
drbehdad@ssu.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity
Yazd University of Medical Sciences

Full name of responsible person
Dr. Shekoufeh Behdad

Position
Professor of Shahid Sadoughi University of Medical Sciences, Yazd

Latest degree
Specialist

Other areas of specialty/work
Anesthesiology

Street address
Shahid Sadoughi Hospital, Ebnesina Blv, Safayieh, Yazd

City
Yazd

Province
Yazd

Postal code
8915887857

Phone
+98 35 3822 4101

Email
drbehdad@ssu.ac.ir

Person responsible for updating data

Contact

Name of organization / entity
Yazd University of Medical Sciences

Full name of responsible person
Dr. Shekoufeh Behdad

Position
professor of Shahid Sadoughi University of Medical Sciences, Yazd

Latest degree
Specialist

Other areas of specialty/work
Anesthesiology

Street address
Shahid Sadoughi Hospital, Ebnesina Blv, Safayieh, Yazd

City
Yazd

Province
Yazd

Postal code
8915887857

Phone
+98 35 3822 4101

Email
drbehdad@ssu.ac.ir

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available

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