

Clinical Trial Protocol

Iranian Registry of Clinical Trials

24 Aug 2026

Comparison of sedative effect of dexmedetomidine and midazolam in patients undergoing EUS procedure outside the operating room

Protocol summary

Study aim

Comparison effect of dexmedetomidine with midazolam in patients undergoing endosonographic procedure on anxiety and pain

Design

126 Patients were randomly divided into 1st intervention group as test group and 2nd intervention group as control group. according to odd or even patient profile number randomization will be done and till end of analysis, statistician will be blinded. sample size were estimated 57 in each group and 10% Loss percentage 63 patient were allocate in each group. this clinical trial will be done in second phase of clinical trial

Settings and conduct

Patient undergoing Endosonography of Imam Khomeini Hospital, after filling consent form enter to study. patient randomly divided into two groups of 63 number. In anesthetic procedure Heart rate, MAPM SpO2 was recorded. after anesthetist procedure analgesia with Ambesh score, sedation with RSS and post operative nausea and vomiting with VAS was recoded

Participants/Inclusion and exclusion criteria

Inclusion criteria: The patients undergoing GI endosonography Exclusion criteria: allergies to the drugs, age <18 or >65 years old, renal or hepatic failure, chronic pain syndromes, unwillingness to participate in the study, cardiovascular disease, respiratory, metabolic, and neurological disorders, difficulties in the airway, class ASA III or IV contraindication of dexmedetomidine, midazolam, propofol, or fentanyl.

Intervention groups

1st intervention group: Received dexmedetomidine 1 ug/kg during 10 minutes with propofol 0.5 mg/kg and fentanyl 1 mg/kg 2nd intervention group: midazolam group received midazolam 0.03 mg/kg with propofol 0.5 mg/kg and fentanyl 1 mg/kg

Main outcome variables

Heart rate (HR), mean arterial pressure (MAP), and oxygen saturation (SpO2), Ramsay Sedation Scale (RSS)

Nausea and vomiting were assessed using Visual Analogue Scale (VAS), analgesia with Ambesh score

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190417043295N1**

Registration date: **2020-02-21, 1398/12/02**

Registration timing: **retrospective**

Last update: **2020-02-21, 1398/12/02**

Update count: **0**

Registration date

2020-02-21, 1398/12/02

Registrant information

Name

Reza Baghbanian

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 61 3222 0168

Email address

baghbanian-r@ajums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-04-21, 1398/02/01

Expected recruitment end date

2019-07-23, 1398/05/01

Actual recruitment start date

2019-04-21, 1398/02/01

Actual recruitment end date

2019-09-23, 1398/07/01

Trial completion date

2019-11-22, 1398/09/01

Scientific title

Comparison of sedative effect of dexmedetomidine and midazolam in patients undergoing EUS procedure outside the operating room

Public title

Comparison sedative effect of Dexmedetomidin & midazolam

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Candidates for gastrointestinal endosonography
Declaration of consent for entry into the study and signature of the consent form Anesthesia ASA class I and II Age range 18 to 65 years

Exclusion criteria:

Renal Failure Liver Failure Sensitivity to the drugs
studied Drug addiction Chronic pain syndromes
Cardiovascular disease Respiratory disease

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

4

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size

Target sample size: **126**

Actual sample size reached: **130**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients are randomly assigned to two groups of dexmedetomidine and midazolam (by using even and odd numbers) and based on the case number.

Blinding (investigator's opinion)

Double blinded

Blinding description

After the injection, the information is recorded in Groups A and B, and until the end of the analyzer's analysis, which group of medication allocation information is inappropriate. Patients are unaware of the type of medication given the injection of the drug in the anesthetic process.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics committee of Ahvaz Jundishapur University of Medical Science

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bahman street-Golestan Ave., Ahvaz

City

ahvaz

Province

Khouzestan

Postal code

15794-61357

Approval date

2019-04-13, 1398/01/24

Ethics committee reference number

IR.AJUMS.REC.1398.002

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

patients undergoing gastrointestinal Endosonography outside the operating room

ICD-10 code

K30

ICD-10 code description

Functional dyspepsia

2**Description of health condition studied****ICD-10 code****ICD-10 code description****Primary outcomes****1****Description**

rate of Sedation (RAMSAY index)

Timepoint

during endo-sonography procedure

Method of measurement

Ramsay Sedation Scale

2**Description**

Pain

Timepoint

Before, during and 1 hour after procedure

Method of measurement

Ambesh Pain score

3**Description**

Nausea and vomiting
Timepoint
Before, during and 1 hour after procedure
Method of measurement
(VAS) Visual analogue scale

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Dexmedetomidine 1 ug/kg inf. for 10 min, propofol 0.5 mg/kg and fentanyl bolous

Category

Treatment - Drugs

2

Description

Control group: Midazolam inf. for 10 min, propofol 0.5 mg/kg and fentanyl bolous

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Ahvaz Imam Khomeini Hospital

Full name of responsible person

Dr. Reza Baghbanian

Street address

24 metery street, east sahely highway, ahvaz

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6193673111

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

Mohammad Badavi

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Web page address

<http://vchresearch.ajums.ac.ir/fa-IR/vchresearch.ajums.ac/4937/page/%D8%B5%D9%81%D8%AD%D9%87-%D8%A7%D8%B5%D9%84%DB%8C-%D9%85%D8%B9%D8%A7%D9%88%D9%86%D8%A>

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

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

Ahvaz University of Medical Sciences

Full name of responsible person

Reza Baghbanian

Position

assistant professor

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

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Person responsible for scientific inquiries

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

crude data file , export analysis file and patient consent form will be available

When the data will become available and for how long

6 month after publish

To whom data/document is available

data files after research and development Vice-chancellor permission will be available for researcher and academic organization

Under which criteria data/document could be used

after research and development Vice-chancellor permission accept DATA file will be send

From where data/document is obtainable

send request from research and development Vice-chancellor web page

What processes are involved for a request to access data/document

send request letter, evaluation in committee, permission issuance, send data file

Comments