

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

27 May 2026

### The sedation effect of midazolam-fentanyl and midazolam-propofol combination in patients with elective upper gastrointestinal endoscopy in Ali ebne Abitaleb Hospital, Zahedan, in 2018

#### Protocol summary

Sedation; satisfaction; hemodynamic instability; apnea

#### Study aim

The sedation effect of midazolam-fentanyl and midazolam-propofol combination in patients with elective upper gastrointestinal endoscopy in Ali ebne Abitaleb Hospital, Zahedan, in 2018

#### Design

Selection and assignment of samples to each treatment group is done by random blocking method. The number of cards in each block will be in the case and control groups, the arrangement of each card of the groups in the block, taking into account the random order with the examples of the permutations, will be arranged. Thus, according to the sample size, 140 people (70 Midazolam + Fentanyl and 70 Midazolam + Propofol) will be identified. Also in this study Patients, Anesthetist, Gastroenterologist are unaware of the allocation of study groups.

#### Settings and conduct

After obtaining written consent, patients who are referred for elective endoscopy are divided into two groups: midazolam + fentanyl (F), midazolam, mcg / kg 15, fentanyl 0.15 mg / kg, and midazolam + propofol (P ) Midazolam 15mcg / kg and Propofol 1mg / kg were given intravenously.

#### Participants/Inclusion and exclusion criteria

inclusion criteria: patient candidated for upper GI endoscopy; age 20-70 years old; ASA class  $\leq 3$ . Exclusion criteria: heart disease AS, IHD , HTN,(HF EF<30%); liver disease (Child-Pugh classification C); renal disease (GFR<60%); lack of patient cooperation; psychiatric disease (Major Depression, Mania, Psychosis); SBP<90; addiction; emergent endoscopy; allergy to egg and soybean.

#### Intervention groups

1- The group receiving midazolam + fentanyl 2. The group receiving midazolam + propofol

#### Main outcome variables

#### General information

##### Reason for update

##### Acronym

ZSGIE

##### IRCT registration information

IRCT registration number: **IRCT20190714044207N1**

Registration date: **2019-07-25, 1398/05/03**

Registration timing: **retrospective**

Last update: **2019-07-25, 1398/05/03**

Update count: **0**

##### Registration date

2019-07-25, 1398/05/03

##### Registrant information

##### Name

Sakineh Sheikh

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 54 3343 4621

##### Email address

sakine.sheikh@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2017-03-21, 1396/01/01

##### Expected recruitment end date

2019-03-19, 1397/12/28

##### Actual recruitment start date

2017-03-21, 1396/01/01

##### Actual recruitment end date

2019-03-19, 1397/12/28  
**Trial completion date**  
2019-03-19, 1397/12/28

### Scientific title

The sedation effect of midazolam-fentanyl and midazolam-propofol combination in patients with elective upper gastrointestinal endoscopy in Ali ebne Abitaleb Hospital, Zahedan, in 2018

### Public title

The sedation effect of midazolam-fentanyl and midazolam-propofol combination in patients with elective upper gastrointestinal endoscopy in Ali ebne Abitaleb Hospital, Zahedan, in 2018

### Purpose

Treatment

### Inclusion/Exclusion criteria

#### Inclusion criteria:

Patient candidated for upper GI endoscopy 20-70 years old ASA class  $\leq 3$

#### Exclusion criteria:

Heart disease AS, IHD , HTN,(HF EF<30%) Liver disease (Child-Pugh classification C) Renal disease (GFR<60%) Lack of patient cooperation Psychiatric Disease (Major Depression, Mania, Psychosis) SBP<90 Addiction Emergent endoscopy Allergy to egg and soybean

### Age

From **20 years** old to **70 years** old

### Gender

Both

### Phase

N/A

### Groups that have been masked

- Participant
- Care provider
- Outcome assessor

### Sample size

Target sample size: **140**

Actual sample size reached: **140**

### Randomization (investigator's opinion)

Randomized

### Randomization description

Selection and assignment of samples to each treatment group is done by random blocking method. The number of cards in each block will be in the case and control groups, the arrangement of each card of the groups in the block, taking into account the random order with the examples of the permutations, will be arranged.

### Blinding (investigator's opinion)

Double blinded

### Blinding description

Patients, Anesthetist, Gastroenterologist are unaware of the allocation of study groups.

### Placebo

Not used

### Assignment

Parallel

### Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee of Zahedan University of Medical Sciences

##### Street address

ZAUMS Main campus, Zahedan, Sistan and Baluchestan, Iran

##### City

Zahedan

##### Province

Sistan-va-Balouchestan

##### Postal code

9816743463

#### Approval date

2019-01-26, 1397/11/06

#### Ethics committee reference number

IR.ZAUMS.REC.1397.244

## Health conditions studied

### 1

#### Description of health condition studied

The sedative effect of the medication on endoscopic digestive system

#### ICD-10 code

R10

#### ICD-10 code description

Abdominal and pelvic pain

### 2

#### Description of health condition studied

The sedative effect of the medication on endoscopic digestive system

#### ICD-10 code

R19

#### ICD-10 code description

Other symptoms and signs involving the digestive system and abdomen

## Primary outcomes

### 1

#### Description

Sedation of drugs in both groups before and after endoscopy

#### Timepoint

From the start of the drug (time 0) and every 5 minutes, it is recorded until the patient is transferred to the recovery room.

#### Method of measurement

Ramsay sedation score (0-5)

## 2

### **Description**

The number of respiration in both groups before and after endoscopy

### **Timepoint**

From the start of the drug (time 0) and every 5 minutes, it is recorded until the patient is transferred to the recovery room.

### **Method of measurement**

Vital signs Monitor device

## 3

### **Description**

The number of heart rate in both groups before and after endoscopy

### **Timepoint**

From the start of the drug (time 0) and every 5 minutes, it is recorded until the patient is transferred to the recovery room.

### **Method of measurement**

Vital signs Monitor device

## 4

### **Description**

Blood Pressure in both groups before and after endoscopy

### **Timepoint**

From the start of the drug (time 0) and every 5 minutes, it is recorded until the patient is transferred to the recovery room.

### **Method of measurement**

Vital signs Monitor device

## 5

### **Description**

Arterial oxygen saturation in both groups before and after endoscopy

### **Timepoint**

From the start of the drug (time 0) and every 5 minutes, it is recorded until the patient is transferred to the recovery room.

### **Method of measurement**

Vital signs Monitor device

## **Secondary outcomes**

### 1

#### **Description**

Comparison of vital signs after endoscopy

#### **Timepoint**

When the patient is transferred to the recovery room

#### **Method of measurement**

Monitoring device of vital signs

### 2

#### **Description**

The satisfaction of sefation of two drug regimens

## **Timepoint**

After Endoscopy End

## **Method of measurement**

Anesthesiology Resident Skill and Experience

## **Intervention groups**

### 1

#### **Description**

Intervention group: IV infusion of midazolam + fentanyl (F), midazolam, mcg / kg 15, fentanyl 0.15 mg / kg

#### **Category**

Treatment - Drugs

### 2

#### **Description**

Intervention group:IV infusion of midazolam + propofol (P ) Midazolam 15mcg / kg and Propofol 1mg / kg

#### **Category**

Treatment - Drugs

## **Recruitment centers**

### 1

#### **Recruitment center**

##### **Name of recruitment center**

Ali ebne Abitaleb Hospital, Zahedan

##### **Full name of responsible person**

Sakineh Sheikh

##### **Street address**

Salamat Blvd., Persian Gulf Highway, Zahedan

##### **City**

Zahedan

##### **Province**

Sistan-va-Balouchestan

##### **Postal code**

9816743463

##### **Phone**

+98 54 3329 5715

##### **Email**

sakine.sheikh@gmail.com

## **Sponsors / Funding sources**

### 1

#### **Sponsor**

##### **Name of organization / entity**

Zahedan University of Medical Sciences

##### **Full name of responsible person**

Doctor Nour Mohamad Bakhshani

##### **Street address**

ZAUMS Main campus, Zahedan, Sistan and Baluchestan, Iran

##### **City**

Zahedan

##### **Province**

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**Phone**

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**Email**

sakine.sheikh@gmail.com

**Grant name**

**Grant code / Reference number**

**Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Zahedan 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**

Zahedan University of Medical Sciences

**Full name of responsible person**

Doctor Sakineh Sheikh

**Position**

Anesthesiology Resident

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Anesthesiology

**Street address**

Salamat Blvd., Persian Gulf Highway, Zahedan

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## Person responsible for scientific inquiries

**Contact**

**Name of organization / entity**

Zahedan University of Medical Sciences

**Full name of responsible person**

Sakineh Sheikh

**Position**

Anesthesiology resident

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Anesthesiology

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Third Intersection, No. 12 Shahid Barfi street, Shahid Barfi Ave

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mmahjoubifard@zaums.ac.ir

## Person responsible for updating data

**Contact**

**Name of organization / entity**

Zahedan University of Medical Sciences

**Full name of responsible person**

Sakineh Sheikh

**Position**

Anesthesiology resident

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Anesthesiology

**Street address**

Third Intersection, No. 12 Shahid Barfi street, Shahid Barfi Ave

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+98 54 3343 4621

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**Email**

mmahjoubifard@zaums.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