# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

29 Jun 2026

## A Comparison of Dexmedetomidine and Propofol in sedation efficacy in patients with elective upper gastrointestinal endoscopy

### Protocol summary

**Study aim**

Determine and comparison of Dexmedetomidine and Propofol in sedation efficacy in patients with elective upper gastrointestinal endoscopy

**Design**

Clinical trial phase3 with 2parallel groups, 3-sided blind, having balanced block randomization with considering gradual patient referral and sample size of 60

**Settings and conduct**

After obtaining written consent, patients who refers to Ali ibn Abitalib hospital for upper endoscopy, randomly assigned to 2groups of Dexmedomidine(D) and Propofol(P). Syringe of drugs will coded by an anesthetist who doesn't interfere with patient's sedation and evaluation process; it coded with a three-digit code, and patients divided according to the code for D or P group. Study is 3-sided blind, and patient, endoscopic physician, and person evaluating the symptoms are blinded to type of treatment group, and only a supervisor who prepares drugs and divides patients according to the code for each group, will know the treatment type received by patients.

**Participants/Inclusion and exclusion criteria**

Enter criteria:patients with elective upper gastrointestinal endoscopy with ASA class ≤3 Not-enter criteria:Having cardiovascular-liver- kidney- psychiatric disease, SBP<90, Drug Addiction, Egg and soy allergy, Emergency endoscopy

**Intervention groups**

In D group, Dexmedetomidine doses of 0.5µg/kg bolus and 0.7-0.5µg/Kg/hr infusion and in P group ,Propofol with doses of 0.5mg/kg bolus and 30µg/Kg/min infusion will given intravenously to patients. Patient hemodynamics will be checked and monitored from start of medication. Relaxation after taking drugs will asked using Ramsay Relaxation Scale from 0-5 (0-Restless,1-Relax,2-Sleepy,3-Confuse but Responded to Verbal Orders,4-No Response to Verbal orders,5-No Response to painful incitements) and will evaluated by an anesthesiologist. After patient becomes alert, sedation satisfaction will be asked.

**Main outcome variables**

Sedation

### General information

**Reason for update**

**Acronym**

**IRCT registration information**

IRCT registration number: **IRCT20190212042688N1**
Registration date: **2019-03-02, 1397/12/11**
Registration timing: **prospective**

Last update: **2019-03-02, 1397/12/11**
Update count: **0**

**Registration date**

2019-03-02, 1397/12/11

**Registrant information**

**Name**

Parnia Sayarfar

**Name of organization / entity**

**Country**

Iran (Islamic Republic of)

**Phone**

+98 54 3329 5796

**Email address**

dr.sf.1458@zaums.ac.ir

**Recruitment status**

**Recruitment complete**

**Funding source**

**Expected recruitment start date**

2019-03-15, 1397/12/24

**Expected recruitment end date**

2019-06-14, 1398/03/24

**Actual recruitment start date**

empty

**Actual recruitment end date**
empty
**Trial completion date**
empty

**Scientific title**
A Comparison of Dexmedetomidine and Propofol in sedation efficacy in patients with elective upper gastrointestinal endoscopy

**Public title**
Comparison of Dexmedetomidine and Propofol in sedation efficacy in patients with elective upper gastrointestinal endoscopy
**Purpose**
Treatment
**Inclusion/Exclusion criteria**
**Inclusion criteria:**
patients with elective upper gastrointestinal endoscopy ASA class ≤3
**Exclusion criteria:**
Having cardiovascular disease (arrhythmia, AS, IHD, HTN, HF or EF <30%) Having liver disease (Child-Pugh Classification C) Having kidney disease (GFR <60%) Having psychiatric illness (Major Depression, Mania, Psychosis) SBP<90 Having Drug Addiction Egg and soy allergy Emergency endoscopy
**Age**
From **20 years** old to **70 years** old
**Gender**
Both

**Phase**
3
**Groups that have been masked**

- Participant
- Care provider
- Outcome assessor

**Sample size**
Target sample size: **60**
**Randomization (investigator's opinion)**
N/A
**Randomization description**
**Blinding (investigator's opinion)**
Triple blinded
**Blinding description**
After obtaining written consent, patients who are elective for upper endoscopy are randomly assigned to two groups that are prescribed to a group of Dexmedomidine (D) and group of Propofol (P). The syringe of drugs will coded by an anesthetist who does not interfere with the patient's sedation and evaluation process; it coded with a three-digit code, and the patients are divided according to the code for the Dexmedomidine or Propofol group. The study is three-sided blind, and the patient, the endoscopic physician, and the person evaluating the symptoms are blind to the type of treatment group, and only a supervisor who prepares the drugs, and divides patients according to the code for each groups will know the type of treatment received by the patient.
**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**
Medical Sciences Campus, Dr. Hesabi Sq.
**City**
Zahedan
**Province**
Sistan-va-Balouchestan
**Postal code**
9816743463
**Approval date**
2019-02-22, 1397/12/03
**Ethics committee reference number**
IR.ZAUMS.REC.1397.455

## Health conditions studied

### 1

**Description of health condition studied**
Upper gastrointestinal disorders
**ICD-10 code**
Z13.810
**ICD-10 code description**
Encounter for screening for upper gastrointestinal disorder

## Primary outcomes

### 1

**Description**
Sedation
**Timepoint**
By monitoring, sedation will be recorded from the start of the drug administration (time 0) and every 5 minutes until the patient transferred to the recovery room.
**Method of measurement**
Relaxation after taking drugs will asked using Ramsay Relaxation Scale from 0-5 (0-Restless,1-Relax,2-Sleepy,3-Confuse but Responded to Verbal Orders,4-No Response to Verbal orders,5-No Response to painful incitements) and will evaluated by an anesthesiologist.

## Secondary outcomes

empty

## Intervention groups

### 1

**Description**
Intervention group: Dexmedetomidine - In D group, Dexmedetomidine doses of 0.5µg/kg bolus and 0.7-0.5µg/Kg/hr infusion will given intravenously to patients.
**Category**
Treatment - Drugs

### 2

**Description**
Intervention group: Propofol - in P group ,Propofol with doses of 0.5mg/kg bolus and 30µg/Kg/min infusion will given intravenously to patients.
**Category**
Treatment - Drugs

## Recruitment centers

### 1

**Recruitment center**
**Name of recruitment center**
Ali ibn Abitalib hospital of Zahedan
**Full name of responsible person**
Mohammad Kazem Momeni
**Street address**
Khalij-e-fars highway, Salamat Blvd., Ali Ibn Abitalib hospital
**City**
Zahedan
**Province**
Sistan-va-Balouchestan
**Postal code**
9816743111
**Phone**
+98 54 3329 5570
**Email**
drkazemmomeni@gmail.com
**Web page address**
http://alihos.zaums.ac.ir/#%D8%A8%DB%8C%D9%85%D8%A7%D8%B1%D8%B3%D8%AA%D8%A7%D9%86%20%D8%B9%D9%84%DB%8C%20%D8%A7%D8%A8%D9%86%20%D8%A7%D8%A8%DB%8C%D8%B7%D8%A7%D9%84%D8%A8%20(%D8%B9)

## Sponsors / Funding sources

### 1

**Sponsor**
**Name of organization / entity**
Zahedan University of Medical Sciences
**Full name of responsible person**
Mohsen Taheri
**Street address**
Medical Sciences Campus, Dr. Hesabi Sq.
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**Email**
taheri@zaums.ac.ir
**Web page address**
http://research.zaums.ac.ir/#%D9%85%D8%B9%D8%A7%D9%88%D9%86%D8%AA%20%D8%AA%D8%AD%D9%82%D9%8A%D9%82%D8%A7%D8%AA%20%D9%88%20%D9%81%D9%86%D8%A7%D9%88%D8%B1%D9%8A
**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**
Parnia Sayarfar
**Position**
Resident
**Latest degree**
Medical doctor
**Other areas of specialty/work**
Anesthesiology
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## Person responsible for scientific inquiries

**Contact**

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## Person responsible for updating data

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**Latest degree**
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## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**
Yes - There is 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

**Title and more details about the data/document**
Only a portion of the information, such as the original outcome information, will be shared.

**When the data will become available and for how long**
6 months after printing the results

**To whom data/document is available**
Data will only be available to researchers working in academic institutions.

**Under which criteria data/document could be used**
Data should only be used to get ideas in future research.

**From where data/document is obtainable**
Referring to the university's research deputy

**What processes are involved for a request to access data/document**
After the registering of request in Research deputy and passing the routine office process, documents will be available up to maximum of one week.

**Comments**