

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

07 Jul 2026

### Comparing the efficacy of dexmedetomidin and ketamin infusion in reducing pain following preoperative propofol injection

#### Protocol summary

##### Study aim

Effect of premedication with dexmedetomidin and ketamin will be evaluated on post injectional pain of propofol before surgery.

##### Design

A total of 100 patients will be selected based on studies and statistical calculations that meet the inclusion criteria after surgery and each patient is discharged from anesthesia, they are divided into two groups of intervention and control. The intervention group will receive dexmedetomidin and the control group will receive ketamin. The study is a randomized, double-blind, placebo-controlled clinical trial.

##### Settings and conduct

Patients will be randomly divided into two groups according to the random number table. control group will receive 0.5 mg/kg ketamin diluted in 20cc normal saline and intervention group will receive the same dose with dexmedetomidin within 10 minutes by infusion. Both ketamin and dexmedetomidine every morning prior to surgery according to the number of operations will be prepared by executor of plan. There will be two kind of envelopes. Envelope A contains syringe containing ketamine and envelope B contains syringe containing dexmedetomidin. Each patient according to whether they are A or B code, will receive these envelopes by anesthesiologist who is unaware of the type of medicine. In this study patient and anesthesiologist are blinded.

##### Participants/Inclusion and exclusion criteria

Entrance: Patients under elective surgery I and II ASA Class. between 15 to 65 years old Exit: Patients with cardiovascular, hepatic, renal disease; need for RSI of anesthesia using sedative drugs in the last 24 hours.

##### Intervention groups

control group will receive 0.5 mg/kg ketamin diluted in 20cc normal saline and intervention group will receive the same dose with dexmedetomidin within 10 minutes by infusion.

#### Main outcome variables

Effect of premedication with dexmedetomidin and ketamin on post injectional pain of propofol.

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20150125020795N8**

Registration date: **2019-12-05, 1398/09/14**

Registration timing: **registered\_while\_recruiting**

Last update: **2019-12-05, 1398/09/14**

Update count: **0**

##### Registration date

2019-12-05, 1398/09/14

##### Registrant information

##### Name

Samad Golzari

##### Name of organization / entity

Tabriz University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 41 3556 6183

##### Email address

golzaris@tbzmed.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2019-10-15, 1398/07/23

##### Expected recruitment end date

2020-04-11, 1399/01/23

##### Actual recruitment start date

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Comparing the efficacy of dexmedetomidin and ketamin infusion in reducing pain following preoperative propofol injection

**Public title**

Effect of Premedication with dexmedetomidin and ketamin in Severity of Pain after Infusion of Propofol.

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

All of Patients who Being a Candidate for Elective Surgery and Based on ASA Classification are 1 or 2 ASA Class

**Exclusion criteria:**

Patients with Cardiovascular, Hepatic and Kidney Disease. Need for Rapid Sequence Induction of Anesthesia. Patients with Psychiatric Disorders. Patients under Prescription of Sedative Drugs in the last 24 hours.

**Age**

From **15 years** old to **65 years** old

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

- Participant
- Care provider

**Sample size**

Target sample size: **100**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

In this study we use balanced randomization that at first four blocks with 9 combination will be formed and blocks will be numbered from 1to9. Compared to the simple randomization method, in this method the size of equilibrium of intervention and placebo groups will be established both during and at the end of study(randomization method is pre and post accidental blocks and will be done by randlist software)

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

The anesthesiologist who has responsible for the patients management of anesthesia will administer the medicine(s) via coded syringes had been prepared previously and will not aware of the injected drug(dexmedetomidin or ketamin), and anesthesia nurse who is responsible for collection of patients information and study variables and is unaware of the administered drug will record the check- list during surgery and in the recovery.Also the patient is unaware of the injected medicine.

**Placebo**

Not used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

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

Ethics committee of Tabriz University of Medical Sciences

**Street address**

Faculty of Medicine, Golgasht Street

**City**

Tabriz

**Province**

East Azarbaijan

**Postal code**

5166614766

**Approval date**

2019-10-15, 1398/07/23

**Ethics committee reference number**

IR.TBZMED.REC.1398.712

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

Post Injectional Pain of Propofol

**ICD-10 code**

T88.59

**ICD-10 code description**

Other complications of anesthesia

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

Post injectional pain of propofol

**Timepoint**

Amount of pain evaluate on 5, 10, 15 and 20 seconds after injection of propofol.

**Method of measurement**

Four Numerical Verbal Rating Scale

**Secondary outcomes**

empty

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

intervention group will receive 0.5 mg/kg dexmedetomidin diluted in 20cc normal saline within 10 minutes intravenously.

**Category**

Treatment - Drugs

**2****Description**

control group will receive 0.5 mg/kg ketamin diluted in 20cc normal saline within 10 minutes intravenously.

**Category**

Treatment - Drugs

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

Emam Reza hospital

**Full name of responsible person**

Samad Eslaam Jamal Golzari

**Street address**

Department of Anesthesiology, Faculty of Medical Sciences, Golgasht Street

**City**

Tabriz

**Province**

East Azarbaijan

**Postal code**

5166614766

**Phone**

+98 41 3334 1994

**Fax**

+98 41 3334 1994

**Email**

golzaris@tbzmed.ac.ir

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

Tabriz University of Medical Sciences

**Full name of responsible person**

Dr Abolghasem Joyban

**Street address**

Vice chancellor for research, Daneshgah street, Tabriz

**City**

Tabriz

**Province**

East Azarbaijan

**Postal code**

5165665931

**Phone**

+98 41 3335 7310

**Fax**

+98 41 3335 7310

**Email**

research-vice@tbzmed.ac.ir

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

Yes

**Title of funding source**

Tabriz 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**

Tabriz University of Medical Sciences

**Full name of responsible person**

Samad Eslam Jamal Golzari

**Position**

Consultant

**Latest degree**

Specialist

**Other areas of specialty/work**

Anesthesiology

**Street address**

Departement of Anesthesiology, Faculty of Medicine, Golgasht Street

**City**

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**Email**

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Tabriz University of Medical Sciences

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**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**

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**

All collected deidentified IPD, IPD collected for the primary outcome measure are to be shared

**When the data will become available and for how long**

Starting 6 months after publication .

**To whom data/document is available**

Documents will be available for people working in academic institutions and also people working in businesses.

**Under which criteria data/document could be used**

There will be no specific limitations to the utilization of the data .

**From where data/document is obtainable**

Dr .Samad Eslam Jamal Golzari, Department of Anesthesiology, Faculty of Medicine, Golgasht Street, Tabriz East Azarbaijan Islamic Republic of Iran Phone+98 413 3341994 Fax+98 41 33341994  
golzaris@tbzmed.ac.ir

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

Correspondence through email only .

**Comments**