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 dexemedetomidine 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
Faculity 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, Ḏaneshgah 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

Tabriz

Province

East Azarbaijan

Postal code

5166614766

Phone

+98 41 3334 1994

Fax

+98 41 3334 1994

Email

golzaris@tbzmed.ac.ir

Person responsible for scientific 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
Department of Anesthesiology, Faculty of Medicine, 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

Person responsible for updating data

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
Department of Anesthesiology, Faculty of Medicine, 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

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