# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

10 Jun 2026

## Effect of Premedication with Methylprednisolon or Dexamethason in Severity of Pain after Infusion of Propofol.

## Protocol summary

**Study aim**

Effect of premedication with methylprednisolon and Dexamethason will be evaluated on post injectional pain of propofol.

**Design**

Sampling is done by continuous method and to come in order of patients. First, an 18 guage intravenous cannula will be embedded on vein of dorsal of hand. Patients are divided to three groups consist on M (methylprednisolon), D (dexamethason) and NS (normal saline). This study is a randomized, double blind clinical trial with control group. Sample size of this study is 120 cases.

**Settings and conduct**

This study is performed in Emam Reza hospital in Tabriz. After embedding of venous catheter and hold up upper limb to 15 seconds, the tornike to close forearm. In the NS group, 5 mililiter normal saline, M group, 125 miligram in 5 mililiter volume with normal saline and D group, 0.25 or 0.5 miligram per kilogram in 5 mililiter volume with normal saline, will be injected. After 30 seconds, the tornike will be opened and 5 mililiter propofol 1% will be injected in 15 seconds. Then, two anesthsiologist will be calculated rate of pain by 4 number verbal rating scale that presented by McCriffick and measurement Rochette criteria in 5, 10,15 and 20 seconds after propofol injection. Patients and two anesthsiologist will be blindfolding.

**Participants/Inclusion and exclusion criteria**

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

**Intervention groups**

Three interventional groups are patients under injection of Methylprednisolon, Dexamethasone and Normal Saline.

**Main outcome variables**

Primary event: incidence of moderate to severe pain after propofol injection. Secondary event: decrease post injectional pain of propofol after premedication with methylprednisolon and dexamethasone.

## General information

**Reason for update**

**Acronym**

**IRCT registration information**

IRCT registration number: **IRCT20150125020795N6**
Registration date: **2019-11-09, 1398/08/18**
Registration timing: **registered_while_recruiting**

Last update: **2019-11-09, 1398/08/18**
Update count: **0**

**Registration date**

2019-11-09, 1398/08/18

**Registrant information**

**Name**
Samad Golzari
**Name of organization / entity**
Tabriz University of Medical Sciences
**Country**
Iran (Islamic Republic of)
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+98 41 3556 6183
**Email address**
golzaris@tbzmed.ac.ir

**Recruitment status**

**Recruitment complete**

**Funding source**

**Expected recruitment start date**

2019-09-23, 1398/07/01

**Expected recruitment end date**

2020-03-19, 1398/12/29

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Effect of Premedication with Methylprednisolon or Dexamethason in Severity of Pain after Infusion of Propofol.

**Public title**

Effect of Premedication with Methylprednisolon or Dexamethason 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
- Outcome assessor

**Sample size**

Target sample size: **120**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

The sampling is done by easy burst method and according to patient referral to operating room. Randomization method is pre and post accidental blocks and will be done by Randlist software.

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

All of Patients do not Know about used Drugs in this Study. Two Anesthesiologist who evaluated clinical response to administerated drugs.

**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**

2019-07-03, 1398/04/12

**Ethics committee reference number**

IR.TBZMED.REC.1398.391

## 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: Patients will be injected 125 milligram Methylprednisolon in 5 milliliter total volume with normal saline.

**Category**

Treatment - Other

### 2

**Description**

Intervention group: Patients will be injected 0.25 or 0.5 milligram Dexamethasone per kilogram of body weight in 5 milliliter total volume that diluted by normal saline.

**Category**
Treatment - Other

**3**

**Description**
Control group: Patients will be injected by 5 milliliter of normal saline.

**Category**
Placebo

## 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

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Tabriz

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golzaris@tbzmed.ac.ir

## Sponsors / Funding sources

**1**

**Sponsor**

**Name of organization / entity**
Vice chancellor for research of Tabriz University of Medical Sciences

**Full name of responsible person**
Dr Abolghasem Joyban

**Street address**
Vice chancellor for research, Ḏaneshgah street, Tabriz

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**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**
Vice chancellor for research of 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

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## Person responsible for scientific inquiries

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## Person responsible for updating data

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**Email**
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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**
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