Clinical Trial Protocol
Iranian Registry of Clinical Trials

12 Nov 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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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 updating data

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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