

Clinical Trial Protocol

Iranian Registry of Clinical Trials

06 Jun 2026

Comparison the effect of granisetron and dexamethasone on intravenous propofol pain

Protocol summary

Summary

This prospective, randomized, double-blind, placebo-controlled study evaluated the effect of dexamethasone and granisetron for reducing the incidence and severity of propofol injection pain. Inclusion criteria: physical status class I and II from the perspective of American Society of Anesthesiologists; dilatation and curettage surgery; 20 to 50 years old. Exclusion criteria: Patients with a history of Allergies to propofol or 5-hydroxytryptamine receptor antagonists or dexamethasone; Patients who received any medication for analgesia or sedation in the past 24 hours; Severe mental disorders; Neuromuscular disease; ischemic heart disease; Uncontrolled hypertension; Renal and hepatic disease; Convulsion disease; Body mass index over 30; Chronic use of any drugs; Gastrointestinal disorders; History of osteoporosis; History of diabetes. One hundred forty one female subjects received 5 mL of preservative-free saline, 1 mg granisetron (mL 5 ml) or 0.15 mg · kg (-1) of dexamethasone (5 ml), intravenously, following exsanguination and occlusion of the veins of the arm. This was followed by a 0.5 mg · kg (-1) injection of propofol. Pain scores, facial grimacing, arm withdrawal, and vocalization were recorded immediately following the injection of propofol. Hemodynamic parameters and SpO_2 were recorded 1, 3, 5 and 10 minutes after propofol injection.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017040427677N6**
Registration date: **2017-05-10, 1396/02/20**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2017-05-10, 1396/02/20

Registrant information

Name

Shahryar Sane

Name of organization / entity

Urmia University of Medical Sciences

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+98 44 3223 4897

Email address

sane.sh@umsu.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice Chancellor for research of Urmia University of Medical Sciences

Expected recruitment start date

2015-12-01, 1394/09/10

Expected recruitment end date

2016-11-30, 1395/09/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison the effect of granisetron and dexamethasone on intravenous propofol pain

Public title

Clinical trial the effect of granisetron and dexamethasone on intravenous propofol pain in patient with dilatation and curettage surgery

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: physical status class I and II from the perspective of American Society of Anesthesiologists; dilatation and curettage surgery; 20 to 50 years old
Exclusion criteria: Patients with a history of Allergies to propofol or 5-hydroxytryptamine receptor antagonists or dexamethasone; Patients who received any medication for analgesia or sedation in the past 24 hours; Severe mental disorders; Neuromuscular disease; ischemic heart disease; Uncontrolled hypertension; Renal and hepatic disease; Convulsion disease; Body mass index over 30; Chronic use of any drugs; Gastrointestinal disorders; History of osteoporosis; History of diabetes

Age

From **20 years** old to **50 years** old

Gender

Female

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **141**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Patients will be divided into three groups by random number table.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Urmia University of Medical Sciences

Street address

Emergent Street, Ershad Avenue

City

Urmia

Postal code

5714783734

Approval date

2015-12-01, 1394/09/10

Ethics committee reference number

ir.umsu.rec.1394.305

Health conditions studied

1

Description of health condition studied

Pain of propofol injection

ICD-10 code

R52.9

ICD-10 code description

Generalized pain NOS

Primary outcomes

1

Description

Pain of propofol injection

Timepoint

Induction of Anesthesia

Method of measurement

visual analog scale

Secondary outcomes

1

Description

Mean pulse Rate

Timepoint

Before injection, 1, 3, 5, 10 minutes after injection

Method of measurement

Electrocardiogram

2

Description

Mean Arterial Blood Pressure

Timepoint

Before injection, 1, 3, 5, 10 minutes after injection

Method of measurement

Non Invasive Blood Pressure

3

Description

os saturation

Timepoint

Before injection, 1, 3, 5, 10 minutes after injection

Method of measurement

Pulse Oximetry

Intervention groups

1

Description

Intervention group 2: Dexamethasone will be prepared in 5 cc syringes and after closing cord randomly injected.

Category

Treatment - Drugs

2

Description

Intervention group 1: Granisetron will be prepared in 5 cc syringes randomly injected.

Category

Treatment - Drugs

3

Description

Control group: Normal Saline will be prepared in 5 cc syringes randomly injected.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Motahhari Hospital

Full name of responsible person

Shahryar Sane

Street address

Kashani Avenue

City

Urmia

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for research of Urmia University of Medical Sciences

Full name of responsible person

Shahryar Sane

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Emergent Street, Resalat avenue, Urmia

City

Urmia

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 Urmia University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Urmia University of Medical Sciences

Full name of responsible person

Shahryar Sane

Position

Assistant Professor

Other areas of specialty/work

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Web page address**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty