

# 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  $o_2sat$  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

###### Country

Iran (Islamic Republic of)

###### Phone

+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 whit 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

**Street address**

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**

**Street address**

Motahhari Hospital, Department of Anesthesiology

**City**

Urmia

**Postal code**

5714615463

**Phone**

+98 44 3222 4777

**Fax**

+98 44 3346 8967

**Email**

sane.sh@umsu.ac.ir; shahryarsane@yahoo.com; dr.sh.sane@gmail.com

**Web page address**

**Person responsible for scientific 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**

**Street address**

Emergent Street, Resalat avenue

**City**

Urmia

**Postal code**

5715781351

**Phone**

+98 44 3223 4897

**Fax**

+98 44 3346 8967

**Email**

sane.sh@umsu.ac.ir; shahryarsane@yahoo.com; dr.sh.sane@gmail.com

**Web page address**

**Person responsible for updating data**

**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****Street address**

Emergent Street, Resalat Avenue

**City**

Urmia

**Postal code**

5714783734

**Phone**

+98 44 3223 4897

**Fax**

+98 44 3346 8967

**Email**

sane.sh@umsu.ac.ir; shahryarsane@yahoo.com;  
dr.sh.sane@gmail.com

**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*