

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

30 May 2026

### Comparison of the efficacy of Metoclopramide and Ondansetron on altering the pain of Etomidate injection under general anesthesia

#### Protocol summary

##### Study aim

Determination of Metoclopramide and Ondansetron effect in relieving pain caused by Etomidate injection in patients under general anesthesia

##### Design

Clinical trial with control group, with parallel groups, double-blind, randomized, phase 2 on 90 patients.

Randomization is also done in a simple way

##### Settings and conduct

The type of study was a three-way randomized blind clinical trial with the control group in Alzahra Hospital of Isfahan in 2009-2010 and was performed on 90 patients in Alzahra Hospital of Isfahan.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients aged 18 to 65 years with grade 1 and 2 anesthesia according to ASA (American society Anesthesia) criteria, candidate for elective surgery and in need of general anesthesia with Etomidate  
Non-entry conditions: Allergy to any of the drugs Etomidate, Ondansetron and Metoclopramide

##### Intervention groups

Group A: Patients in this group receive 10 mg of Metoclopramide and then 10 minutes later 5 ml of normal saline. Group B: Patients in this group receive 8 mg of Ondansetron and then 10 minutes later 5 ml of normal saline. Group C: Patients in this group receive 5 ml of normal saline and then 10 minutes later receive 5 ml of normal saline. All groups are given one cc of 2% Lidocaine ampoule equivalent to 20 mg, then Etomidate 3 mg at a rate of one cc per second (counting 1001, 1002, etc.) and pain intensity will be measured immediately.

##### Main outcome variables

Severe pain due to atomoditis injection

#### General information

##### Reason for update

##### Acronym

#### IRCT registration information

IRCT registration number: **IRCT20160307026950N32**

Registration date: **2021-03-07, 1399/12/17**

Registration timing: **prospective**

Last update: **2021-03-07, 1399/12/17**

Update count: **0**

#### Registration date

2021-03-07, 1399/12/17

#### Registrant information

##### Name

Behzad Nazemroaya

##### Name of organization / entity

Isfahan University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 31 3212 3543

##### Email address

behzad\_nazem@med.mui.ac.ir

#### Recruitment status

**Recruitment complete**

#### Funding source

#### Expected recruitment start date

2021-04-04, 1400/01/15

#### Expected recruitment end date

2021-07-06, 1400/04/15

#### Actual recruitment start date

empty

#### Actual recruitment end date

empty

#### Trial completion date

empty

#### Scientific title

Comparison of the efficacy of Metoclopramide and Ondansetron on altering the pain of Etomidate injection under general anesthesia

**Public title**

The effect of Metoclopramide and Ondansetron on Etomidate injection pain

**Purpose**

Prevention

**Inclusion/Exclusion criteria****Inclusion criteria:**

Aged 18 to 65 years criteria Anesthesia grade 1 and 2 according to ASA (American society Anesthesia)

Candidates for elective surgery and Require general anesthesia with atomiditis

**Exclusion criteria:**

Allergy to the Etomidate Allergy to the Metocloramide Allergy to the Ondansetrone

**Age**

From **18 years** old to **65 years** old

**Gender**

Both

**Phase**

3

**Groups that have been masked**

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

**Sample size**

Target sample size: **90**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Randomization is done in a simple way; In this way, the eligible patients enter groups B, A and C, respectively, depending on the time of their arrival, and this sequence is repeated until the number of patients reaches 30 in each group.

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

This is a two-blind study in which the clinical caregiver and the person injecting the drug are different from the person performing the intervention and are unaware of the intervention. Also, patients in each group are explained that in order to reduce the pain caused by Types of intervention are applied to them without explaining the type of intervention. Therefore, patients are not aware of the type of intervention and are kept blind.

**Placebo**

Used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Isfahan University of Medical Sciences Committe for Ethics in Biomedical Research

**Street address**

Hezar Jarib St

**City**

Isfahan

**Province**

Isfahan

**Postal code**

8174673461

**Approval date**

2020-08-11, 1399/05/21

**Ethics committee reference number**

IR.MUI.MED.REC.1399.521

**Health conditions studied****1****Description of health condition studied**

Pain due to Etomidate injection

**ICD-10 code****ICD-10 code description****Primary outcomes****1****Description**

Pain due to atomeditis injection

**Timepoint**

Immediately after the intervention

**Method of measurement**

By scoring with VAS (visual analog scale) from 1 (painless) to 2 (worst pain imaginable)

**Secondary outcomes**

empty

**Intervention groups****1****Description**

Intervention group A: Patients in this group after receiving the surgical bed and monitoring connection receive 10 mg of Metoclopramide and 10 minutes later 5 ml of distilled water, then Etomidate is injected and the patient's pain is measured immediately.

**Category**

Prevention

**2****Description**

Intervention group B: Patients in this group after receiving the surgical bed and monitoring connection

receive 10 mg of Metoclopramide and 10 minutes later 5 ml of distilled water, then Etomidate is injected and the patient's pain is measured immediately.

**Category**

Prevention

**3****Description**

Control group C: Patients in this group receive 5 ml of distilled water after being placed on a surgical bed and monitoring connection and 5 minutes later receive 5 ml of distilled water, then Etomidate is injected and the patient's pain is measured immediately.

**Category**

Placebo

**Recruitment centers****1****Recruitment center****Name of recruitment center**

Alzahra hospital

**Full name of responsible person**

Behzad Nazemoroaya

**Street address**

Soffeh boulevard, Shahid Keshvari highway

**City**

Isfahan

**Province**

Isfahan

**Postal code**

8174675731

**Phone**

+98 31 3620 2020

**Email**

behzad\_nazem@med.mui.ac.ir

**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Esfahan University of Medical Sciences

**Full name of responsible person**

Shaghayegh Haghjoo

**Street address**

Hezar Jarib

**City**

Isfahan

**Province**

Isfahan

**Postal code**

8174673461

**Phone**

+98 31 3668 0048

**Email**

research@mui.ac.ir

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

No

**Title of funding source**

Vice Chancellor for Research, Isfahan 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**

Esfahan University of Medical Sciences

**Full name of responsible person**

Ziba Zekavat

**Position**

Medical student

**Latest degree**

Medical doctor

**Other areas of specialty/work**

General Practitioner

**Street address**

Hezar Jarib

**City**

Isfahan

**Province**

Isfahan

**Postal code**

8146713543

**Phone**

+98 31 3620 2020

**Email**

behzad\_nazem@med.mui.ac.ir

**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Esfahan University of Medical Sciences

**Full name of responsible person**

Behzad Nazem roaya

**Position**

Professor assistant of Anesthesia and Intensive care intensive care

**Latest degree**

Specialist

**Other areas of specialty/work**

Anesthesiology

**Street address**

Hezar Jarib

**City**

Isfahan  
**Province**  
Isfahan  
**Postal code**  
8146713543  
**Phone**  
+98 31 3620 2020  
**Email**  
behzad\_nazem@med.mui.ac.ir

## Person responsible for updating data

### Contact

**Name of organization / entity**  
Esfahan University of Medical Sciences  
**Full name of responsible person**  
Leyla Rafiei  
**Position**  
Nurse Anesthesia  
**Latest degree**  
Bachelor  
**Other areas of specialty/work**  
Anesthesiology  
**Street address**  
Hezar Jarib  
**City**  
Isfahan  
**Province**  
Isfahan

**Postal code**  
8146713543  
**Phone**  
+98 31 3620 2020  
**Email**  
leylarafiei943@gmail.com

## 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