

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

Comparison of the effects of preventive injection of 4 mg and 8 mg Ondansetron doses on pain caused by Etomidate injection in patients under general anesthesia

Protocol summary

Study aim

Comparison of the effect of preventive injection of 4 mg and 8 mg Ondansetron on pain caused by Etomidate injection

Design

Clinical trial with control group, with parallel groups, double-blind, randomized, phase 3 on 60 patients. Lottery and sealed envelopes are used for randomization.

Settings and conduct

This is a randomized double-blind clinical trial that will be performed on 60 patients undergoing general anesthesia with Etomidate at Al-Zahra Hospital in Isfahan; After University Ethics Committee approval and patient satisfaction, patients were randomly assigned to the groups. In each group, the desired intervention is applied and the patient's clinical symptoms are recorded. The person who is performing the intervention would be different from the evaluator and they do not know the type of intervention. In spite of the fact that Patients are aware of the study, they are not aware of the type of intervention so they are all blind.

Participants/Inclusion and exclusion criteria

Inclusion criteria: ASA class I and II, age 18 to 60 years, general anesthesia candidate with Etomidate and patient informed consent to participate in the study Exclusion criteria: heart disease, psychologic disease and diabetes, allergic to drugs used, addiction

Intervention groups

Intervention group A: They receive 4 mg Ondansetron 2 minutes before inducing anesthesia Intervention group B: They receive 8 mg Ondansetron 2 minutes before inducing anesthesia Control group C: They receive 4 ml distilled water 2 minutes before inducing anesthesia, then all three groups will be induced under anesthesia with 20 mg Etomidate, and their clinical signs will be recorded.

Main outcome variables

Pain caused by Etomidate

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20160307026950N38**

Registration date: **2021-10-25, 1400/08/03**

Registration timing: **registered_while_recruiting**

Last update: **2021-10-25, 1400/08/03**

Update count: **0**

Registration date

2021-10-25, 1400/08/03

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

2021-10-23, 1400/08/01

Expected recruitment end date

2022-01-21, 1400/11/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effects of preventive injection of 4 mg and 8 mg Ondansetron doses on pain caused by Etomidate injection in patients under general anesthesia

Public title

The effect of Ondansetron on pain caused by Etomidate injection

Purpose

Prevention

Inclusion/Exclusion criteria**Inclusion criteria:**

Patients 18 to 60 years Grade I and II in ASA criteria (American Society of Anesthesia) Candidate for general anesthesia with Etomidate

Exclusion criteria:

Patients with Heart Disease Patients with Psychologic disease Allergic to drugs used in the study Taking sedatives or painkillers 24 hours before anesthesia Addiction to drugs

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

3

Groups that have been masked

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

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

This is a simple randomized clinical trial in which patients are entered the study groups by lottery; The medicines and placebo are placed in the sealed, opaque and similar form packets which are coded. Each code is also written on a piece of paper, folded, and placed inside a box. After entering the operating room, each patient takes one of the papers out of the box; The pocket with the same number is the intervention that will apply for him. This process continues till the number of patients will reach the desired one.

Blinding (investigator's opinion)

Double blinded

Blinding description

This is a double-blind clinical trial; In this way, before obtaining consent, patients are studied but do not know which group they will be in and therefore are blind. Also, the nurse who injects the drug and the researcher who records the patient's symptoms do not know the type of drug and are blind.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics Committee in Biomedical Research, Isfahan University of Medical Sciences

Street address

Hezar Jarib St

City

Isfahan

Province

Isfahan

Postal code

8174673461

Approval date

2021-07-01, 1400/04/10

Ethics committee reference number

IR.MUI.MED.REC.1399.443

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

Pain caused by Etomidate

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

The amount of pain caused by Etomidate injection

Timepoint

During the injection until 30 seconds

Method of measurement

Faces Pain Rating Scale (FPRS)

Secondary outcomes**1****Description**

Heart Rate

Timepoint

Before injection, immediately after injection, 5 and 10 minutes after Etomidate injection and then every 15 minutes until the end of the operation.

Method of measurement

ECG monitoring

2

Description

Moderate arterial blood pressure

Timepoint

Before injection, immediately after injection, 5 and 10 minutes after Etomidate injection and then every 15 minutes until the end of the operation.

Method of measurement

Barometer

3

Description

Arterial blood oxygen saturation

Timepoint

Before injection, immediately after injection, 5 and 10 minutes after Etomidate injection and then every 15 minutes until the end of the operation.

Method of measurement

Pulse oximeter

4

Description

Duration of anesthesia

Timepoint

From the beginning of anesthesia to the end of recovery

Method of measurement

Clock

Intervention groups

1

Description

Intervention group A: In this group, eligible patients, after being placed on a surgical bed and monitoring connection, receive 300 ml of normal saline per hour, then they are injected with 4 mg of Ondansetron made by Exir Pharmaceutical Company in 2 minutes and 2 minutes later, they are induced under anesthesia with 20 mg of Etomidate made by Abu Reihan company and the patient's clinical symptoms are recorded.

Category

Prevention

2

Description

Intervention group B: In this group, eligible patients, after being placed on a surgical bed and monitoring connection, receive 300 ml of normal saline per hour, then they are injected with 8 mg of Ondansetron made by Exir Pharmaceutical Company in 2 minutes and 2 minutes later, they are induced under anesthesia with 20 mg of Etomidate made by Abu Reihan company and the patient's clinical symptoms are recorded.

Category

Prevention

3

Description

Control group C: In this group, eligible patients, after being placed on a surgical bed and monitoring connection, receive 300 ml of Normal Saline per hour, then they are injected with 4 ml of distilled water and 2 minutes later under anesthesia. With 20 mg of Etomidate made by Abu Reihan company and the patient's clinical symptoms are recorded.

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?

Yes

Title of funding source

Esfahan 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
Ruzbeh Akhavanfar
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
Roozbeh1372@gmail.com

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
carentensive 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 Anesthetist
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