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, psycho logic 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

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Iran (Islamic Republic of)

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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
Isfehan
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
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Soffeh boulevard, Shahid Keshvari highway
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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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

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Latest degree
Specialist

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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