Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 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
Isfehan
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

Isfehan

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

Isfehan

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

Isfehan

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 carentensive care

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

Street address

Hezar Jarib

City

Isfahan

Province

Isfehan

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

Isfehan

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