

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 Jul 2026

Comparison of the effectiveness of Fentanyl administration and Valsalva maneuver in relieving pain caused by Etomidate injection to induce general anesthesia

Protocol summary

Study aim

Comparison of the effect of Valsalva maneuver and Fentanyl injection on pain caused by Etomidate injection

Design

Clinical trial with control group, with parallel groups, double-blind, randomized, phase 3 per 96 patients. Randomization will be done by lottery.

Settings and conduct

This study is a double-blind randomized clinical trial that will be performed on patients undergoing general anesthesia at Isfahan Al-Zahra Hospital after obtaining an ethics license. Intervention groups. In each group, one of the interventions is applied and the results are recorded. The person performing the intervention, the patients and the person recording the results are uninformed and blind. The data is encrypted and therefore the data analyzer is also blind.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age 18 to 65 years, Candidate of General Anesthesia, ASA Class I and II Anesthesia, Able to perform Valsalva maneuver Exclusion criteria: history of mental illness, Cardiorespiratory, chronic pain disorders, use of painkillers, allergy to Etomidate and Fentanyl, history of drug use.

Intervention groups

Intervention group A: Patients in this group are assigned to perform a Valsalva maneuver by blowing into a plastic tube attached to a sphygmomanometer hand and raising the mercury column to 30 mmHg for at least 20 seconds just before the etomidate injection. Fentanyl injection is given falsely. Intervention group B: Patients in this group receive Fentanyl intravenously at a dose of 2 Micrograms per kilogram of body weight 3 minutes before receiving etomidate, and a plastic tube with an open end is placed in the patient's mouth to perform a fake Valsalva maneuver.

Main outcome variables

Pain due to Etomidate injection

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20160307026950N33**

Registration date: **2021-03-30, 1400/01/10**

Registration timing: **registered_while_recruiting**

Last update: **2021-03-30, 1400/01/10**

Update count: **0**

Registration date

2021-03-30, 1400/01/10

Registrant information

Name

Behzad Nazemroaya

Name of organization / entity

Isfahan University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-01-04, 1399/10/15

Expected recruitment end date

2021-06-05, 1400/03/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Comparison of the effectiveness of Fentanyl administration and Valsalva maneuver in relieving pain caused by Etomidate injection to induce general anesthesia

Public title
The effect of Fentanyl injection and Valsalva maneuver on pain caused by Etomidate injection

Purpose
Prevention

Inclusion/Exclusion criteria
Inclusion criteria:
 Patients 18 to 65 years Candidate for General Anesthesia ASA Class I and II Anesthesia Able to perform Valsalva maneuver
Exclusion criteria:
 History of mental, Cardiorespiratory and chronic pain disorders Use of painkillers History of allergy to Etomidate and Fentanyl History of drug use

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: **96**

Randomization (investigator's opinion)
Randomized

Randomization description
Randomization is done by block method; If the number of patients in both groups is the same, the first patient enters one of the groups by lottery, then from the second patient, patients enter one of the groups one by one according to their arrival time, so that the sample size reaches the required number in each Reach the group.

Blinding (investigator's opinion)
Double blinded

Blinding description
This is a randomized, double-blind clinical trial; Patients are explained that in order to reduce the pain caused by anesthesia injection, two interventions of Fentanyl injection and Valsalva maneuver are performed on them and depending on their group, only one of the interventions is performed completely, but patients are of the intervention type. The one who will be fully applied are unaware. Also, the person injecting the drug and the person recording the patient's symptoms are unaware of the type of intervention applied. The data is encrypted and therefore the analyzers are also blind.

Placebo
Used

Assignment
Parallel

Other design features
In this study, the two groups are compared in terms of intervention and the control group does not exist separately.

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

City

Isfahan

Province

Isfahan

Postal code

8174673461

Approval date

2020-08-22, 1399/06/01

Ethics committee reference number

IR.MUI.MED.REC.1399.635

Health conditions studied

1

Description of health condition studied

The pain caused by injection of Etomidate

ICD-10 code

G89

ICD-10 code description

Pain, not elsewhere classified

Primary outcomes

1

Description

The amount of pain caused by Etomidate injection

Timepoint

Before intervention, after intervention, immediately after injection and 1, 2, 3, 5, 10 and 15 minutes after injection of initial dose of Etomidate

Method of measurement

withdrawal response score

Secondary outcomes

1

Description

Blood Pressure

Timepoint

Before intervention, after intervention, immediately after injection and 1, 2, 3, 5, 10 and 15 minutes after injection of initial dose of atomidite

Method of measurement

Manometer

2

Description

Heart Rate

Timepoint

Before intervention, after intervention, immediately after injection and 1, 2, 3, 5, 10 and 15 minutes after injection of initial dose of atomidite

Method of measurement

ECG

3

Description

Blood oxygen saturation

Timepoint

Before intervention, after intervention, immediately after injection and 1, 2, 3, 5, 10 and 15 minutes after injection of initial dose of atomidite

Method of measurement

Pulse Oximeter

Intervention groups

1

Description

Intervention group A: In this group, patients first receive 2 cc of normal saline intravenously and after 3 minutes, perform the Valsalva maneuver by blowing in a plastic tube (where the hole is closed on the tube) for at least 26 seconds. At the end of the Valsalva maneuver, Etomidate injection is started.

Category

Prevention

2

Description

Intervention group B: Patients in this group first receive Fentanyl at a dose of 2 micrograms per kilogram of body weight intravenously and 3 minutes later a plastic tube is placed in the patient's mouth and the patient blows into the tube (while the hole is inserted on Is open on the pipe). Etomidate injection is started after 26 seconds.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Alzahra hospital

Full name of responsible person

Behzad Nazemoroaya

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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?

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
Golshan Mazahery

Position
Medical student

Latest degree
Medical doctor

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Latest degree
Specialist

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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