

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Jul 2026

A comparative study of lidocaine, lidocaine and melatonin and Valsalva maneuver, lidocaine and Valsalva maneuver to reduce the pain associated with administration of etomidate

Protocol summary

Study aim

A comparative study of lidocaine, lidocaine and melatonin and Valsalva maneuver, lidocaine and Valsalva maneuver to reduce the pain associated with administration of etomidate

Design

Open label randomized clinical trial, with three parallel groups, randomized with block randomization, phase 3, on 135 patients overall.

Settings and conduct

The study is a clinical trial, in which cases are divided into 3 groups by block randomization: 1. Valsalva maneuver, melatonin injection and lidocaine injection 2. lidocaine, and 3. Valsalva maneuver along with prescription of lidocaine. It will be carried out in January and February 2021, in Alzahra hospital, Isfahan, Iran. After informed consent, candidates for sedation with etomidate are divided in 3 groups and their demographic information and visual analog scores are recorded. Only data analyst is blinded in this study.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 1. Physical class I or II 2. Age between 18 to 65 years old 3. etomidate administration as sedative. Exclusion criteria: patient with sepsis; history of allergic reaction; kidney function disease; liver function disease; patient with history of hypertension and uncontrolled diabetes.

Intervention groups

1- performing Valsalva maneuver, melatonin injection and lidocaine injection; 2- Lidocaine injection 3- Lidocaine injection while the patient is performing Valsalva maneuver.

Main outcome variables

Pain

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20160307026950N31**

Registration date: **2021-01-27, 1399/11/08**

Registration timing: **prospective**

Last update: **2021-01-27, 1399/11/08**

Update count: **0**

Registration date

2021-01-27, 1399/11/08

Registrant information

Name

Behzad Nazemroaya

Name of organization / entity

Isfahan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 31 3212 3543

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-02-03, 1399/11/15

Expected recruitment end date

2021-03-05, 1399/12/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty	street
Scientific title	City
A comparative study of lidocaine, lidocaine and melatonin and Valsalva maneuver, lidocaine and Valsalva maneuver to reduce the pain associated with administration of ethomidate	Esfahan
	Province
	Isfahan
	Postal code
	8174673461
Public title	Approval date
A comparison of lidocaine, lidocaine and melatonin and Valsalva maneuver, lidocaine and Valsalva maneuver to reduce the pain associated with administration of ethomidate	2021-01-18, 1399/10/29
	Ethics committee reference number
	IR.MUI.MED.REC.1399.968
Purpose	Health conditions studied
Prevention	<u>1</u>
Inclusion/Exclusion criteria	Description of health condition studied
Inclusion criteria:	Local injection site pain
Physical condition in ASA class I and II Age 18 to 65 years old Candidates for general anesthesia with ethomidate	ICD-10 code
Exclusion criteria:	G89.18
Patient with sepsis History of allergic reactions Kidney function disease Liver function disease Patient with hypertension and uncontrolled diabetes	ICD-10 code description
	Other acute postprocedural pain
Age	Primary outcomes
From 18 years old to 65 years old	<u>1</u>
Gender	Description
Both	Local ethomidate injection site pain measured by visual analog scale
Phase	Timepoint
2	Right after injection
Groups that have been masked	Method of measurement
No information	1)Visual analog scale 2) Objective physician-assessed pain score
Sample size	Secondary outcomes
Target sample size: 135	empty
Randomization (investigator's opinion)	Intervention groups
Randomized	<u>1</u>
Randomization description	Description
Block randomization is used in this study to divide cases in 3 groups. SAS algorithm was used to perform blocked randomization.	Intervention group: first inject lidocaine and melatonin, then the patient is asked to perform Valsalva maneuver at the time of ethomidate injection
Blinding (investigator's opinion)	Category
Not blinded	Prevention
Blinding description	<u>2</u>
Placebo	Description
Used	Intervention group: intravenous Lidocaine bolus injection of 1mg/Kg of body weight, over 2-3 minutes
Assignment	Category
Parallel	Prevention
Other design features	<u>3</u>
	Description
Secondary Ids	
empty	
Ethics committees	
<u>1</u>	
Ethics committee	
Name of ethics committee	
Isfahan University of Medical Sciences Committe for Ethics in Biomedical Research	
Street address	
Isfahan University of Medical Sciences, Hezar Jerib	

Intervention group: the patient is asked to perform Valsalva maneuver at the time of etomidate injection. In the meantime intravenous Lidocaine bolus dose of 1mg/Kg of body weight, is injected over 2-3 minutes.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Alzahra hospital

Full name of responsible person

Behzad Nazem Roaya

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Alzahra hospital, Soffe blvd.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Shaghayegh Haghjoo

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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

Behzad Nazem Roaya

Position

Associate Professor

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

There is a possibility that our subjects would not be
willing to consent to their data being shared.

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not 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

Not applicable

Data Dictionary

Not applicable