Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

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

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 ethomidate

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 devided 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 ethomidate 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.ethomidate 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)
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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

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

Public title
A comparation of lidocaine, lidocaine and melatonin and Valsalva maneuver, lidocaine and Valsalva maneuver to reduce the pain associated with administration of ethomidate

Purpose
Prevention

Inclusion/Exclusion criteria
Inclusion criteria:
Physical condition in ASA class I and II Age 18 to 65 years old Candidates for general anesthesia with ethomidate
Exclusion criteria:
Patient with sepsis History of allergic reactions Kidney function disease Liver function disease Patient with hypertension and uncontrolled diabetes

Age
From **18 years** old to **65 years** old

Gender
Both

Phase
2

Groups that have been masked
No information

Sample size
Target sample size: **135**

Randomization (investigator's opinion)
Randomized

Randomization description
Block randomization is used in this study to devide cases in 3 groups. SAS algorithm was used to perform blocked randomization.

Blinding (investigator's opinion)
Not blinded

Blinding description

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
Isfahan University of Medical Sciences, Hezar Jerib street
City
Esfahan
Province
Isfehan
Postal code
8174673461

Approval date
2021-01-18, 1399/10/29

Ethics committee reference number
IR.MUI.MED.REC.1399.968

Health conditions studied

1

Description of health condition studied
Local injection site pain

ICD-10 code
G89.18

ICD-10 code description
Other acute postprocedural pain

Primary outcomes

1

Description
Local ethomidate injection site pain measured by visual analog scale

Timepoint
Right after injection

Method of measurement
1)Visual analog scale 2) Objective physician-assessed pain score

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: first inject lidocaine and melatonin, then the patient is asked to perform Valsalva maneuver at the time of ethomidate injection

Category
Prevention

2

Description
Intervention group: intravenous Lidocaine bolus injection of 1mg/Kg of body weight, over 2-3 minutes

Category
Prevention

3

Description

Intervention group: the patient is asked to perform Valsalva maneuver at the time of ethomidate 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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Person responsible for updating data

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Other areas of specialty/work
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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