

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 Jul 2026

Comparative effect of sufentanil and dexmedetomidin on myoclonus incidence and pain induced by anesthesia with etomidate: a double blind clinical trial study

Protocol summary

Study aim

Evaluation of the effect of premedication with sufentanil and intramedullary doxamethomidine on reducing the incidence of myoclonus and pain due to induction of general anesthesia with otitis media and its comparison with control group

Design

A clinical trial with 3 groups, three randomized blinds is performed on 108 patients.

Settings and conduct

This study is a double-blind randomized clinical trial with a control group that is conducted in Al-Zahra Educational and Medical Center affiliated to Isfahan University of Medical Sciences in 2018-2019. The target population of the study will be candidates for surgeries admitted to the hospital

Participants/Inclusion and exclusion criteria

۵۲۹/۵۰۰۰ Inclusion and exclusion criteria: A- Entry criteria: 1- Patients 18 to 60 years old 2- ASA class 1 and 2 3- Candidate for surgery and needs general anesthesia 4 - Lack of heart and liver failure, mental illness, neurological diseases, allergies to opioids 5- Not receiving painkillers and sedatives during the last 24 hours 6- Agreeing to participate in the study B- Criteria for not entering: 1. Age less than 18 years or more than 65 years 2. Drug addiction C- Criteria for leaving the study: 1- Lack of cooperation of the person to answer the questions 2- Occurrence of drug allergies 3- 3-change in anesthesia method

Intervention groups

The first group was injected with 0.1 micrograms per kilogram intravenously and the second group was injected with 0.5 mg / kg dexmedetomidine intravenously Special is done.

Main outcome variables

Medium arterial pressure Myoclonus recovery the pain Spo2

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20101211005362N25**

Registration date: **2020-07-30, 1399/05/09**

Registration timing: **retrospective**

Last update: **2020-07-30, 1399/05/09**

Update count: **0**

Registration date

2020-07-30, 1399/05/09

Registrant information

Name

Mohammadreza Safavi

Name of organization / entity

Anesthesiology and Critical Care Research Center, Isfahan University of Medical Sciences, Isfahan

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-07-21, 1397/04/30

Expected recruitment end date

2019-09-21, 1398/06/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparative effect of sufentanil and dexmedetomidin on myoclonus incidence and pain induced by anesthesia with etomidate: a double blind clinical trial study

Public title

Comparative effect of sufentanil and dexmedetomidin on myoclonus incidence and pain induced by anesthesia with etomidate

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Patients 18 to 60 years ASA Class 1 and 2 Candidate for surgery and in need of general anesthesia Agree to participate in the study

Exclusion criteria:

heart and liver failure, mental illness, neurological diseases, opioid allergy Drug addiction

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Care provider
- Investigator

Sample size

Target sample size: **108**

Randomization (investigator's opinion)

Randomized

Randomization description

Eligible additions were assigned to the three study groups using randomized block methods with a size of 6 blocks and using random allocation software.

Blinding (investigator's opinion)

Triple blinded

Blinding description

In the present study, the injector and the data collector also had no information and the participants did not know the type of drug received. The injector has no knowledge of the type of drug (blinding) and the data collector has no knowledge of the type of drug (both sides of the blind). Premedication drugs are coated in 10 ml syringes with prior coding. After administering 100% oxygen, premedication is given intravenously over a period of 2 minutes. The second anesthesiologist, who is not aware of grouping, then records the myoclonus movements and pain of the patients based on scoring. The first anesthesiologist injects only medications and collects information such as pain and myoclonus, mean arterial pressure, heart rate, blood oxygen saturation percentage at the general time 0, 5, 10, 15, 30, and 60 minutes after atomiditis. They do not have any information about the type of medicine they received.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Isfahan University of Medical Sciences

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Approval date

2020-05-08, 1399/02/19

Ethics committee reference number

IR.MUI.MED.REC.1399.126

Health conditions studied**1****Description of health condition studied**

pain

ICD-10 code

Y48.2

ICD-10 code description

premedication anesthetic

Primary outcomes**1****Description**

Myoclonus

Timepoint

Minutes 0 - 5 - 10 - 15 - 30 - 60 - 60 after atomiditis injection

Method of measurement

Pulse oximeter

Secondary outcomes

empty

Intervention groups**1****Description**

In the present study, there are two intervention groups and one control group. 1- In the first intervention group, sufentanil is injected intravenously at the rate of 0.1 micrograms per kilogram

Category

Treatment - Drugs

2**Description**

Intervention group: 2- In the second intervention group, dexmedetomidine is injected intravenously at the rate of 0.5 micrograms per kilogram.

Category

Treatment - Drugs

3**Description**

Control group: 3- In the control group, distilled water is injected in the amount of 5 cc.

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Al-Zahra Hospital

Full name of responsible person

Mohammad Reza Safavi

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Esfahan University of Medical Sciences

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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

Mohammadreza Safavi

Position

Professor of anesthesia

Latest degree

Specialist

Other areas of specialty/work

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

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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

Not applicable

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

Person responsible for updating data**Contact****Name of organization / entity**

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Zohreh Niknejad

Position

Medical Student

Latest degree

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Other areas of specialty/work