Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

The effect of ondansetron on reduction of etomidate-induced myoclonic movements in patients with ophthalmic surgery

Protocol summary

Study aim
The effect of ondansetron on myoclonic reduction induced by Etomidate

Design
Clinical trial with control group, with parallel groups, randomized, phase 3 on 60 patients. The block method is used for randomization.

Settings and conduct
The study included 60 adult patients (over 18 years old) who are candidates for elective ophthalmic surgery with ASA I-II who are under general anesthesia for elective ophthalmic surgery in Mshhad Khatam Hospital. Patients entered the study after obtaining informed consent and explaining the study. Sampling method is available sampling method. Patients are treated with 5cc/kg fluid for 10minutes before induction and routine monitoring includes pulse Oximetry,ECG,NIBP and capnography are performed for patients. Patients with random allocation (block method) in 2 groups receiving ondansetron (4mg (IV) (group O) or control group with 5cc of N/S (IV) before They receive from Etomidate, are placed and receive this drug as a prodrug 180 seconds before induction with Etomidate at the rate of 0.3 mg/kg. The incidence of myoclonus is assessed by resident of anesthesia who is not aware of the groups,(triple blind) and the severity of myoclonus with a score between 0 and 3 are measured.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Adults (over 18 years old) ASAII-I who are candidates for elective ophthalmic surgery. And consent to participate in the study. Exclusion criteria: Patients with adrenal dysfunction Drug allergy Mental disorders Neuromuscular disease Seizures Electrolyte disorders Surgery with a high risk of nausea and vomiting such as strabismus

Intervention groups
Patients with randomized allocation (block method) are divided into 2 groups receiving ondansetron (4 mg (IV) (group O) or the control group receiving 5cc of normal saline (IV) before Etomidate

Main outcome variables
Incidence and Intensity of myoclonic movements

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20190510043545N2**
Registration date: **2021-10-02, 1400/07/10**
Registration timing: **prospective**

Last update: **2021-10-02, 1400/07/10**
Update count: **0**

Registration date
2021-10-02, 1400/07/10

Registrant information

Name
seyed javad purafzali firuzabadi

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-10-07, 1400/07/15

Expected recruitment end date
2021-11-06, 1400/08/15

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The effect of ondansetron on reduction of etomidate-induced myoclonic movements in patients with ophthalmic surgery

Public title
The effect of ondansetron on reduction of etomidate-induced myoclonic movements

Purpose
Prevention

Inclusion/Exclusion criteria

Inclusion criteria:
Adults (over 18 years old) ASAII-I who are candidates for elective ophthalmic surgery. And consent to participate in the study.

Exclusion criteria:
Patients with adrenal dysfunction Drug allergy Mental disorders Neuromuscular disease Seizures Electrolyte disorders Surgery with a high risk of nausea and vomiting such as strabismus

Age
From **18 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
Participants will be randomly divided into two groups using a random blocking method with a size of 4 blocks using Software Allocation Random (RAS) software with a 1: 1 allocation ratio by the non-involved person in the study. To conceal the allocation, closed opaque envelopes will be prepared and numbered according to the number of samples. Envelope preparation and random allocation sequencing will be performed by the non-research person.

Blinding (investigator's opinion)
Triple blinded

Blinding description
Participants are divided into two groups receiving normal saline (control group) and ondansetron (intervention group) as prodrug. The participant is injected intravenously and does not know which group he is in. The person assigning the samples to the groups does not know the assigned group. The person examining the incidence and severity of myoclonus is not aware of the participant's assigned group, and the analyzer is not aware of the assigned group.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Mashhad University of Medical Sciences

Street address
Knowledge and Health City – In the end of Shahid Fakouri Blvd (In front of Fakouri 94) – Mashhad - Iran

City
Mashhad

Province
Razavi Khorasan

Postal code
91778-99191

Approval date
2021-06-15, 1400/03/25

Ethics committee reference number
IR.MUMS.MEDICAL.REC.1400.234

Health conditions studied

1

Description of health condition studied
etomidate-induced myoclonic movements

ICD-10 code
G25.3

ICD-10 code description
Myoclonus

Primary outcomes

1

Description
Intensity of myoclonus

Timepoint
The occurrence and severity of myoclonus are controlled from the time of injection to 90 seconds after atomiditis injection.

Method of measurement
myoclonic movements score

Secondary outcomes

empty

Intervention groups

1

Description
The ondansetron group received 4 mg (IV) (group O) before Etomidate and received the drug as a prodrug 180 seconds before induction with Etomidate at a dose of 0.3 mg / kg.This drug is used as a single dose of 4 mg intravenously 180 seconds before Etomidate injection. Ondansetron is a serotonin antagonist. In all participants, the drug will be used by one company.

Category
Prevention

2

Description
Control group: The control group received 5 cc of normal saline (IV) before Etomidate and received the drug as a prodrug 180 seconds before induction with Etomidate at the rate of 0.3 mg / kg.Normal saline will be injected as a placebo.

Category
Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center
Khatam hospital

Full name of responsible person
Mohamad Alipour

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Mashhad - Abu Talib crossroads to Ferdowsi Square - Shahid Gharani St. 41

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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?
Yes

Title of funding source
Mashhad 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
Mashhad University of Medical Sciences

Full name of responsible person
Mohamad Alipour

Position
Associate professor of anesthesiology

Latest degree
Specialist

Other areas of specialty/work
Anesthesiology

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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