Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Comparison of the effects of Ephedrine and Ketamine with Placebo on onset time of Atracurium in patients under general anesthesia

Protocol summary

Study aim
Comparison of the effects of Ephedrine and Ketamine with Placebo on the onset time of Atracurium in patients undergoing general anesthesia

Design
141 patients, aged 15 _ 65 years, undergoing elective surgery were include in this clinical trial study. By using statistical software, patients were randomly divided into three groups with 47 patients each. All patients gave their informed conset and the study protocol was approved by the local ethics comittee. This study includes two parallel case groups and one control group . This is a phase 2_3 clinical trial in a double-blind, randomized fashion.

Settings and conduct
After obtaining informed conset, 141 patients aged 15-65 years old, with the ASA classification 1 or 2, scheduled for elective surgery at Shariati hospital, were enrolled in the study. All of the patients were premedicated with midazolam, fentanyl and propofol. patients in Ketamine group received 0.5 mg/kg Ketamine, patients in Ephedrine group received 0.05 mg/kg Ephedrine, and as placebo, 5cc of Normal Saline was given to patients in the control group. 30 seconds after the first injection, 0.5 mg/kg Atracurium was administered to all the patients. 2 minutes after the administration of fentanyl, Neuromuscular blockade monitoring on the arm was initiated.

Participants/Inclusion and exclusion criteria
Inclusion criteria : Patients with the ASA classes 1 or 2 Patients undergoing elective surgery Exclusion criteria : Patients with BMI less than 16.5 or above 35 Patients with mallampati score 3 or more History of HTN or IHD within one year prior to the surgery

Intervention groups
Patients are randomly divided into three groups: patients receiving Ephedrine, patients receiving Ketamine, and the control group that are receiving Normal Saline as placebo. The onset time of Atracurium will be compared between the groups.

Main outcome variables
The onset time of Atracurium in seconds

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20190721044285N1**
Registration date: **2019-07-31, 1398/05/09**
Registration timing: **prospective**

Last update: **2019-07-31, 1398/05/09**
Update count: **0**

Registration date
2019-07-31, 1398/05/09

Registrant information

Name
Mohammad Ghasemi

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 28 3333 4646

Email address
mhd.ghasemi371@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-08-06, 1398/05/15

Expected recruitment end date
2019-08-21, 1398/05/30

Actual recruitment start date
empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effects of Ephedrine and Ketamine with Placebo on onset time of Atracurium in patients under general anesthesia

Public title

Effect of Ephedrine and Ketamine on onset time of Atracurium

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with ASA score 1 or 2 Patients undergoing elective surgery 8 hours fasting at least

Exclusion criteria:

Patients with BMI between 16.5 to 35 Liver or kidney disease Patients with mallampati test 3 or more Patients with HTN or IHD in one year ago

Age

From **15 years** old to **65 years** old

Gender

Both

Phase

2-3

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size

Target sample size: **141**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients were randomly divided with Random Allocation software

Blinding (investigator's opinion)

Double blinded

Blinding description

Patients have informed consent for intervention, but they dont know which group they are in. The outcome evaluator is also unaware of the patient group The data analyst will analyse the data in 3 groups that the drug used by each group is unknown

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Tehran University of Medical Sciences

Street address

Shariati hospital, North Amir Abad Ave

City

Tehran

Province

Tehran

Postal code

3415719451

Approval date

2019-05-29, 1398/03/08

Ethics committee reference number

IR.TUMS.MEDICINE.REC.1398.108

Health conditions studied

1

Description of health condition studied

Intubation

ICD-10 code

T88.4

ICD-10 code description

Failed or difficult intubation

Primary outcomes

1

Description

Shorten the onset time of the effect of Atracurium

Timepoint

2 minutes after the administration of fentanyl until 2 response in Train Of Four at 10 seconds intervals

Method of measurement

Nerve Stimulator (train of four)

Secondary outcomes

empty

Intervention groups

1

Description

First Intervention group: In this group, each patient is given 0.05 mg/kg Ephedrine intravenous before injection of Atracurium

Category

Prevention

2

Description

Intervention group: In this group, each patient is given 0.5 mg/kg Ketamine intravenous before injection of

Atracurium

Category

Prevention

3

Description

Control group: In this group each patient is given 5cc Normal Saline intravenous as a placebo before injection of Atracurium

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Shariati hospital

Full name of responsible person

Mohammad Ghasemi

Street address

Shariati hospital , North Amir Abad

City

Tehran

Province

Tehran

Postal code

3415719451

Phone

+98 28 3333 4646

Email

mhd.ghasemi371@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Shokofeh Nikfar

Street address

TUMS, porsina Ave, 16 Azar Blvd

City

Tehran

Province

Tehran

Postal code

3415719451

Phone

+98 28 3333 4646

Email

mhd.ghasemi371@gmail.com

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Tehran 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

Tehran University of Medical Sciences

Full name of responsible person

Mohammad Ghasemi

Position

Medico

Latest degree

Medical doctor

Other areas of specialty/work

General Practitioner

Street address

Shariati hospital, North Amir Abad Ave

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Phone

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mhd.ghasemi371@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

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Person responsible for updating data

Contact

Name of organization / entity

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

The Analysis of the main outcome data will be published

When the data will become available and for how long

6 months later

To whom data/document is available

Reseachers

Under which criteria data/document could be used

__

From where data/document is obtainable

Mohammad ghasemi Tel : 09127852900

What processes are involved for a request to access data/document

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Comments