

# 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 consent and the study protocol was approved by the local ethics committee. 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 consent, 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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**Person responsible for scientific inquiries**

**Contact**

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**Person responsible for updating data**

**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**

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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**

**Comments**