

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

Comparison of the effects of etomidate versus ketamine on outcome of adult patients with multiple trauma requiring rapid sequence intubation

Protocol summary

Study aim

Comparison the effects of etomidate versus ketamine on outcome of adult patients with multiple trauma requiring rapid sequence intubation

Design

In this double-blind clinical trial study, there are two study regimens: ketamine and etomidate which are used as induction agents at the emergency department for critical patients requiring rapid sequence intubation. 80 patients according to the inclusion and excluding criteria enter the study and are randomized by specifying a code and using a randomized numeric table.

Settings and conduct

Adult patients with multiple trauma in critical clinical conditions requiring tracheal intubation at the emergency department enter the study and drug regimens which have been filled in syringes (with special blinded codes) are administered to the patients by the nurse for induction of anesthesia.

Participants/Inclusion and exclusion criteria

Inclusion criteria: All multiple trauma adult patients referring to emergency department of Kowsar hospital requiring rapid sequence tracheal intubation because of decreased level of consciousness or ineffective breathing or circulatory shock. Exclusion criteria: drug allergy; elevated intracerebral or intraocular pressure; hypertension (Blood Pressure \geq 160/110 mm Hg); severe endocrine disorders (hyperthyroidism, adrenal insufficiency); active lung disease; tracheal stenosis; obstructive sleep apnea; airway obstruction; laryngospasm; pregnancy or lactation.

Intervention groups

1-Ketamine 2- etomidate

Main outcome variables

death at emergency department or during hospital admission, duration of survival days during hospital admission, ventilator free days, ICU-free days, vasopressor-free days

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20171106037280N3**

Registration date: **2019-01-28, 1397/11/08**

Registration timing: **registered_while_recruiting**

Last update: **2019-01-28, 1397/11/08**

Update count: **0**

Registration date

2019-01-28, 1397/11/08

Registrant information

Name

hamed sotoude

Name of organization / entity

Kurdistan university of medical sciences

Country

Iran (Islamic Republic of)

Phone

+98 87 3366 2027

Email address

h-sotude@razi.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-01-10, 1397/10/20

Expected recruitment end date

2019-04-21, 1398/02/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effects of etomidate versus ketamine on outcome of adult patients with multiple trauma requiring rapid sequence intubation

Public title

The effects of etomidate and ketamine on outcome of adult patients with multiple trauma requiring tracheal intubation

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

All adult multiple trauma patients referring to Sanandaj Kowsar Hospital emergency department requiring rapid sequence tracheal intubation

Exclusion criteria:

allergy to drugs elevated intracerebral or intraocular pressure hypertension (Blood Pressure \geq 160/110 mm Hg) severe endocrine disorders active lung disease tracheal stenosis obstructive sleep apnea airway obstruction laryngospasm pregnancy or lactation

Age

From 18 years old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: 80

Randomization (investigator's opinion)

Randomized

Randomization description

simple randomization with allocating random numbers to patients and selecting the drug based on that number.

Blinding (investigator's opinion)

Double blinded

Blinding description

Patients and medications are marked with numbers which are unknown for patients and investigators, at the end of the study it is revealed that which number is representative of which medication for each patient.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Kurdistan University of Medical Sciences

Street address

Pasdaran St., Kurdistan University of Medical Sciences, Research Department

City

Sanandaj

Province

Kurdistan

Postal code

6618634683

Approval date

2018-03-14, 1396/12/23

Ethics committee reference number

IR.MUK.REC.1396/376

Health conditions studied

1

Description of health condition studied

intubation in trauma patient

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Death at emergency department or during admission at hospital

Timepoint

During emergency department and hospital admission

Method of measurement

Death declaration at his/her documents

2

Description

Duration of survival days during hospital admission

Timepoint

During emergency or hospital admission (from admission and intubation until death)

Method of measurement

Number of survival days

3

Description

ICU-free days

Timepoint

During hospital admission from intubation to 28 days after admission (ICU-discharge point until 28 days after admission)

Method of measurement

Number of ICU-free days

4

Description

Ventilator-free days

Timepoint

During hospital admission from intubation to 28 days after admission (the time of weaning from mechanical ventilation until 28 days after admission)

Method of measurement

Number of ventilator-free days

5

Description

Vasopressor free days

Timepoint

During hospital admission from intubation to 28 days after admission (the time of stopping vasopressor infusion until 28 days after admission)

Method of measurement

Number of vasopressor-free days

Secondary outcomes

1

Description

Number of transfused packed-RBCs

Timepoint

During the first 48 hours from admission

Method of measurement

Number of transfused packed-RBCs documented on patient file

2

Description

Sepsis incidence

Timepoint

During the first 28 days from admission

Method of measurement

Having 2 or more criteria form SIRS associated with an infection focus during the first 28 days from admission

Intervention groups

1

Description

Intervention group1:ketamine: ketamine 3 mg/kg IV infusion, administered once at the beginning of the intervention for induction during rapid sequence intubation.

Category

Treatment - Drugs

2

Description

Intervention group2:etomidate: etomidate 0.3 mg/kg IV infusion, administered once at the beginning of the intervention for induction during rapid sequence intubation.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Kowsar hospital emergency department

Full name of responsible person

Hamed Sotoude

Street address

Sanandaj, pasdaran st., kowsar hospital, emergency department

City

Sanandaj

Province

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Postal code

6618434683

Phone

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Email

H-sotoude@razi.tums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Sanandaj University of Medical Sciences

Full name of responsible person

Hamed Sotoude

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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

Sanandaj 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

Sanandaj University of Medical Sciences

Full name of responsible person

Hamed Sotoude

Position

Assistant professor

Latest degree

Specialist

Other areas of specialty/work

Emergency Medicine

Street address

Sanandaj, Pasdaran st., Kowsar hospital, emergency department

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Person responsible for scientific inquiries

Contact

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Person responsible for updating data

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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

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

Title and more details about the data/document

The collected data about outcome will be disclosed

When the data will become available and for how long

The data will be published 1 year after the results.

To whom data/document is available

Students and physicians and lecturers

Under which criteria data/document could be used

Data can be used under copyright rules.

From where data/document is obtainable

Data will be in access by sending an e-mail to H-sotude@razi.tums.ac.ir.

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

The data would be reachable for whom with a qualified letter from research department of their university or institute.

Comments