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>= 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 hypertention (Blood Pressure>= 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
Kurdistan
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6618434683
Phone
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Email
H-sotude@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
Street address
Sanandaj, pasdaran st., kowsar hospital, emergency department
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Email
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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

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Sanandaj, Pasdaran st., Kowsar hospital, emergency department

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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