Clinical Trial Protocol
Iranian Registry of Clinical Trials

03 Jul 2026

A comparison of the effects of Heart Rate Control with Amiodarone and esmolol on Hemodynamic and Clinical Outcomes in Patients with Septic Shock

Protocol summary

Study aim

Comparison of the effect of amiodarone and osmolol on heart rate control Comparison of the effect of amiodarone and osmolol on the need for vasopressor Comparison of the effect of amiodarone and osmolol on the need for fluid therapy

Design

Patients based on clinical and hemodynamic conditions in the presence of sepsis shock Receiving norepinephrine(NEP) for more than 24 hours with a mean blood pressure(MAP) above 65 mm Hg despite appropriate fluid therapy and heart rate above 95 . The sample size of each group in this study is 15 patients.

Settings and conduct

This study is a clinical trial study performed in the intensive care unit of Sinai Hospital.

Participants/Inclusion and exclusion criteria

inclusion criteria: Patients over 18 years; Suffering from sepsis shock requires receiving vasopressor; Heart rate above 100 beats per minute; Gaining informed consent; Cardiac index above 2.5; Absence of arrhythmia Exclusion criteria: Previous treatment with beta-blocker or amiodarone in the last 48 hours; Patient with valvular problems; Pregnancy; Pulmonary fibrosis; Retinoid; Known pulmonary pressure; valvular disorder; Aortic aneurysm; CPR post conditions; ARDS

Intervention groups

Patients are divided into two groups. In the first group, amiodarone and in the second group, esmolol is started as a heart rate control drug.

Main outcome variables

Medium arterial pressure; stroke volume index; Cardiac output index; heart rate; systemic Vascular resistance; fluid requirement; Vasopressor need

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190929044923N1**
Registration date: **2021-01-16, 1399/10/27**
Registration timing: **retrospective**

Last update: **2021-01-16, 1399/10/27**
Update count: **0**

Registration date

2021-01-16, 1399/10/27

Registrant information

Name

masoud khataminia

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 4446 7101

Email address

masoodkhataminia@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-12-22, 1398/10/01

Expected recruitment end date

2020-12-21, 1399/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
A comparison of the effects of Heart Rate Control with Amiodarone and esmolol on Hemodynamic and Clinical Outcomes in Patients with Septic Shock

Public title
A Comparison of the effects of amiodarone and osmolol in patients with septic shock

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
septic shock receiving vasopressor despite adequate fluid therapy Heart rate above 100 beats per minute for no apparent reason (such as fever, agitation, pain, anemia, and hypovolemia that should be treated before starting medication and hemodynamic tests) Cardiac index above 2.5 liters / minute per square meter Absence of arrhythmia

Exclusion criteria:
treatment with beta-blocker or amiodarone in the last 48 hours Patient with heart valve problems Pregnancy Pulmonary fibrosis Hypo / Hyperthyroidism Known pulmonary hypertension History of amiodarone intolerance Post CPR conditions Aortic aneurysm ARDS with PaO2 / FiO2 less than 150

Age
From **18 years** old

Gender
Both

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **30**

Randomization (investigator's opinion)
Not randomized

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Vice Chancellor for Research and Technology, Tehran University of Medical Sciences

Street address
Keshavarz Boulevard, corner of Quds Street, Central University Organization, sixth floor, Vice Chancellor for Research and Technology

City
tehran

Province
Tehran

Postal code
1996835113

Approval date
2019-07-23, 1398/05/01

Ethics committee reference number
IR.TUMS.VCR.REC.1398.426

Health conditions studied

1

Description of health condition studied
septic shock

ICD-10 code
A41.9

ICD-10 code description
Sepsis, unspecified organism

Primary outcomes

1

Description
stroke volume index

Timepoint
0,6,12,24 hour after adminstration

Method of measurement
uscom

2

Description
cardiac output index

Timepoint
0 612 24 hours after adminstration

Method of measurement
uscom

3

Description
heart rate

Timepoint
0 6 12 24 hours after adminstration

Method of measurement
heart rate monitoring device

4

Description
vascular resistance

Timepoint
0, 6 12 24 after adminstration

Method of measurement
uscom

5

Description
acid lactic
Timepoint
baseline and 24hours after administration
Method of measurement
laboratory analysis

6

Description
mean arterial pressure
Timepoint
0, 6 12 24 after adminstration
Method of measurement
monitoring device

7

Description
Vasopressor intake rate
Timepoint
0, 6 12 24 after adminstration
Method of measurement
View Cardex

8

Description
The amount of fluid received
Timepoint
baseline and 24hours after administration
Method of measurement
View Cardex

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: The first intervention included amiodarone group therapy: After measuring the patient's hemodynamic characteristics, cardiac output, vascular resistance by uscom, patients are treated with amiodarone. The dose of amiodarone in these patients according to Guidalin is 150 ACC / AHA mg for 10 minutes and then infusion of 1-0.5 mg / minute. The dosage of this drug is adjusted so that patients are divided into the following groups based on heart rate. - If the heart rate is more than 100 beats per minute, continuous infusion of 1 mg / minute is started. - If the heart rate is more than 90 beats and less than 100 beats per minute, continuous infusion of 0.5 mg / min is started. If the target heart rate is not reached, it is increased by 1 mg / min every 20 minutes. If it is more than 70 times and less than 80 times per minute, the infusion is reduced to 0.5 mg per minute. - If the heart rate is more than 60 times and less than 70 times per minute, the infusion is 1 mg / minute.
Category
Treatment - Drugs

2

Description
Control group: esmolol treatment control group: In this group, after measuring the patient's hemodynamic characteristics, cardiac output, vascular resistance by uscom device, patients are treated with esmolol. The goal is a heart rate of 85 beats per minute. The esmolal dose of the infusion in these patients is 20 µg / kg / min. The dosage of this drug is adjusted in such a way that patients are divided into the following groups based on heart rate. - If the heart rate is more than 100 beats per minute, it starts with 20 µg / kg / min. - If the heart rate Start between 100-90 times per minute esmolol starts at a dose of 10 µg / kg / min. - If the target heart rate is not reached, it will increase by 20 micrograms / kg every 20 minutes. If the heart rate is between 80-70 beats per minute, the infusion is reduced to 10 µg / kg / min. If the heart rate is between 70-60 beats per minute, the infusion is reduced to 20 µg / kg / min. If the following is observed, the infusion of esmolol is stopped: - If the heart rate drops below 60: The infusion is stopped for 20 minutes and then continues with an increase in heart rate above 70 beats per minute at half the previous speed . ScvO2 ≤ 60% OR LV ejection fraction ≤ 25% OR Cardiac Index ≤ 2.0 L / min / m2 - In case of bronchospasm, the drug is permanently discontinued and It does not start again.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Šina hospital
Full name of responsible person
masoud khataminia
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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
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
masood khataminia
Position
resident
Latest degree
Medical doctor
Other areas of specialty/work
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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
Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Yes - There is 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

Title and more details about the data/document

The raw data obtained from this study, an an excel or SPSS file will be provided to them at the request of the project supervisor or the reviewer of the article

When the data will become available and for how long

After writing the initial draft of the article

To whom data/document is available

project supervisor or the reviewer of the article upon their request

Under which criteria data/document could be used

If re-analyis of the data is needed

From where data/document is obtainable

Written correspondence with the first executor of the project

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

Written correspondence with the first executor of the project if necessary to re-analyze the data

Comments