

Clinical Trial Protocol

Iranian Registry of Clinical Trials

07 Jul 2026

Comparison of the Effectiveness of the metoprolol in mortality rate reduction in septic patients admitted to ICU ward

Protocol summary

Study aim

Determining the effect of Metoral in reducing the death of septic patients admitted to the intensive care unit.

Design

Septic patients over 18 years of age admitted to ICU wards by simple randomization with random number table divided into intervention and control groups, clinical trial, with parallel group, one-way blind, phase 2 on 36 patients.

Settings and conduct

Septic patients in ICU of Mousavi Hospital were simple randomly divided into 2 groups, the intervention group, receiving 25 mg metoral tablets every eight hours for 7days one-sided blind.others not receive metoral.Then lab indicators and the 14-day mortality of patients are determined

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients over 18 years of age admitted to the ICU wards of Ayatollah Mousavi Hospital in Zanjan with a diagnosis of sepsis that has not been diagnosed for more than forty-eight hours. Inclusion criteria: Age under 18 years. Pregnancy. More than forty-eight hours have passed since the diagnosis of sepsis. Acute heart failure, AV block, bradycardia (heart rate below 70 beats per minute), heart shock, hypotension (systolic pressure below 90 mm Hg), pulmonary edema, patient sinus syndrome, ventricular dysfunction, acute bronchospasm, asthma, bronchitis Chronic Obstructive Pulmonary Disease (COPD), Emphysema, Pulmonary Disease, Peripheral Artery Disease, Raynaud's Phenomenon, Vasospastic Angina, Lactation, Pheochromocytoma, Myasthenia Gravis, Liver Disease

Intervention groups

Intervention group: septic patients in the intensive care unit, who were selected by simple randomization, receive 25 mg oral metoral tablets every eight hours for seven days with vital sign control.Control group:patients met the same criteria but did not receive metoral.

Main outcome variables

Blood pressure; Heart rate; Left ventricular ejection fraction; Sequential Organ Failure Assessment; 14 day mortality

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180804040695N2**

Registration date: **2022-02-20, 1400/12/01**

Registration timing: **prospective**

Last update: **2022-02-20, 1400/12/01**

Update count: **0**

Registration date

2022-02-20, 1400/12/01

Registrant information

Name

Mohammadreza Zeraati

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 24 3313 0000

Email address

mohammadrezazeraati@zums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-03-21, 1401/01/01

Expected recruitment end date

2022-05-22, 1401/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty
Trial completion date
empty

Scientific title
Comparison of the Effectiveness of the metoprolol in mortality rate reduction in septic patients admitted to ICU ward

Public title
The effect of metoprolol on reducing mortality in septic patients

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
over 18 y admitted in the ICU wards of Ayatollah Mousavi Hospital in Zanjan Diagnosis of sepsis less than forty-eight hours after diagnosis

Exclusion criteria:
Pregnancy Acute heart failure AV block bradycardia (heart rate below 70 beats per minute) heart shock hypotension (systolic pressure below 90 mm Hg) pulmonary edema sick sinus syndrome ventricular dysfunction acute bronchospasm asthma bronchitis Chronic Obstructive Pulmonary Disease (COPD) Emphysema Pulmonary Disease Peripheral Artery Disease Raynaud's Phenomenon Vasospastic Angina Breast feeding Pheochromocytoma Myasthenia Gravis Liver Diseases

Age
From **18 years** old

Gender
Both

Phase
2-3

Groups that have been masked

- Participant

Sample size
Target sample size: **36**

Randomization (investigator's opinion)
Randomized

Randomization description
Simple randomization using coin toss. Sampling is available and included in the study with the patient's hospitalization, and since we have only two small 18-digit intervention and control groups, assignment to each group is simple random and by tossing coins and taps for each patient.

Blinding (investigator's opinion)
Single blinded

Blinding description
The patient under intervention will be unaware of the type of treatment due to the reduced level of consciousness in the intensive care unit.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Zanjan University of Medical Sciences

Street address

Zanjan University of Medical Sciences , Azadi Square, Zanjan, Iran

City

Zanjan

Province

Zanjan

Postal code

4515613191

Approval date

2021-10-16, 1400/07/24

Ethics committee reference number

IR.ZUMS.REC.1400.298

Health conditions studied

1

Description of health condition studied

sepsis

ICD-10 code

A41

ICD-10 code description

other sepsis

Primary outcomes

1

Description

Mortality rate of septic patients

Timepoint

Two weeks after the start of the intervention

Method of measurement

Refer to the medical file

2

Description

Heart rate

Timepoint

Every six hours until the end of a week

Method of measurement

cardiac monitoring

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Receiving routine treatment of sepsis in addition to receiving 25 mg oral metoprolol tablets of Alborz Drug Company every eight hours for seven days with regular control of vital signs.

Category

Treatment - Drugs

2

Description

Control group: Receive routine treatment of sepsis.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Ayatollah Mousavi Specialized and Sub-Specialized Educational and Medical Center

Full name of responsible person

Mohammad Reza Zeraati

Street address

Ayatollah Mousavi Specialized and Sub-Specialized Educational and Medical Center, Gavazang Road, Zanzan Town

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4513956184

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mohammadrezazeraati@zums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Zanzan University of Medical Sciences

Full name of responsible person

dr. Maziar Peyda

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Mousavihospital@zums.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Zanzan 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

Zanzan University of Medical Sciences

Full name of responsible person

Mohammad Reza Zeraati

Position

Associate Professor

Latest degree

Subspecialist

Other areas of specialty/work

Anesthesiology

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Person responsible for scientific inquiries

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Zanzan University of Medical Sciences

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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

publishing article

When the data will become available and for how long

Over the next year

To whom data/document is available

Public access

Under which criteria data/document could be used

For research

From where data/document is obtainable

Magazine office

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

Searching in Internet

Comments