

Clinical Trial Protocol

Iranian Registry of Clinical Trials

05 Jul 2026

Study of the effect of dexmedetomidine on the outcome of patients with septic shock admitted to the intensive care unit, a randomized single blind placebo controlled trial

Protocol summary

Study aim

Study of the effect of dexmedetomidine on the outcome of patients with septic shock admitted to the intensive care unit

Design

In this research, which designed a parallel single-blind randomized clinical trial, 66 eligible patients randomize to receive one of the interventions. A code is allocated to each participants

Settings and conduct

This study is conducted in the intensive care unit of Imam Khomeini and Razi educational hospital in Sari and Qaemshahr respectively between 2018-19. The patient and register person are blind to the interventions.

Participants/Inclusion and exclusion criteria

The criteria for entering this study are patients with septic shock aged over 18 years who are treated with norepinephrine or vasopressor. Exclusion criteria include patients with uncontrolled diabetes mellitus, patients with grade 2 and 3 ventricular block, patients with sick sinus syndrome, patients with COPD history (arterial oxygen demand below 60 mmHg), patients with history of beta-blockers, patients with hypovolemia And patients with severe liver failure.

Intervention groups

The intervention group will receive Dexmedetomidine 0.8 microgram/kg/hr up to 12 hours. In control group Normal Saline 6cc/kg/hr will start for 12 hours.

Main outcome variables

Improvement of the patient's clinical symptoms (within 12 hours of infusion and 7 days later) include: viability of the patient, separation from the ventilator, reduction of delirium levels, improvement of systolic and diastolic blood pressure and heart rate, reduction of the dose required for epinephrine and morphine and midazolam

General information

Reason for update

Acronym

MICUS

IRCT registration information

IRCT registration number: **IRCT20100107003014N22**

Registration date: **2019-02-25, 1397/12/06**

Registration timing: **registered_while_recruiting**

Last update: **2019-02-25, 1397/12/06**

Update count: **0**

Registration date

2019-02-25, 1397/12/06

Registrant information

Name

Shahram Ala

Name of organization / entity

Mazandaran University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-07-23, 1397/05/01

Expected recruitment end date

2019-09-21, 1398/06/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Study of the effect of dexmedetomidine on the outcome of patients with septic shock admitted to the intensive care unit, a randomized single blind placebo controlled trial

Public title

effect of dexmedetomidine on the outcome of septic shock patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with septic shock patients treated with norepinephrine or vasopressor Patients over the age of 18 years

Exclusion criteria:

uncontrolled diabet melitus patients with severe hepatic failure hypovolemic patients patients with a history of beta blocker use patients with a history of COPD patients with sick sinus syndrome patients with heart block 2,3

Age

From **18 years** old

Gender

Both

Phase

3

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size

Target sample size: **66**

Randomization (investigator's opinion)

Randomized

Randomization description

patients will be divided into two groups by block randomization allocation with random table number. Each patient will be given a dedicated code.33 patients will be in the control group and 33 patients will be in the recipient group.

Blinding (investigator's opinion)

Single blinded

Blinding description

The investigator who register patient's hemodynamic changes, is blind to which patients receive which intervention.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

ethics.research.ac.ir

Street address

Moalem Sq

City

Sari

Province

Mazandaran

Postal code

33971-48157

Approval date

2019-02-20, 1397/12/01

Ethics committee reference number

IR.MAZUMS.REC.1397.249

Health conditions studied

1

Description of health condition studied

Septic shock

ICD-10 code

R57.8

ICD-10 code description

Other shock

Primary outcomes

1

Description

clinical success

Timepoint

Every hour to 12 hours and then 7 days after intervention

Method of measurement

Data collecting form

Secondary outcomes

1

Description

Heart rate changes

Timepoint

Every hour up to 12 hours

Method of measurement

Recorder monitor

2

Description

Mean arterial pressure changes

Timepoint

Every hour up to 12 hours

Method of measurement

Recorder monitor

3

Description

Systolic blood pressure changes

Timepoint

Every hour up to 12 hours

Method of measurement

Recorder monitor

4

Description

Diastolic blood pressure changes

Timepoint

Every hour up to 12 hours

Method of measurement

Recorder monitor

5

Description

Norepinephrine dose

Timepoint

Every hour up to 12 hours

Method of measurement

Data collecting form

6

Description

Morphine dose

Timepoint

Every hour up to 12 hours

Method of measurement

Data collecting form

7

Description

Midazolam dose

Timepoint

Every hour up to 12 hours

Method of measurement

Data collecting form

8

Description

SOFA score

Timepoint

Prime of entrance and 7days later

Method of measurement

Data collecting form

9

Description

GCS

Timepoint

Prime of entrance

Method of measurement

Data collecting form

10

Description

APACHE II

Timepoint

Prime of entrance

Method of measurement

Data collecting form

11

Description

Delirium

Timepoint

Prime of entrance

Method of measurement

Data collecting form

12

Description

Dependence on ventilator

Timepoint

7days after intervention

Method of measurement

Data collecting form

13

Description

Survival of patients

Timepoint

7 days after intervention

Method of measurement

Data collecting form

Intervention groups

1

Description

Intervention group: Dexmedetomidine 0.8 micro/kg/h for 12 hours

Category

Treatment - Drugs

2

Description

Control group: Serum Normal saline 6 cc/kg/hr up to 12 hr

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Khomeini hospital

Full name of responsible person

Shahram Ala

Street address

Razi street

City

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3313148166

Phone

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Email

info@emamhospital.ir

Web page address

Yes

Title of funding source

Sari 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

2**Recruitment center****Name of recruitment center**

Razi hospital

Full name of responsible person

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Web page address**Person responsible for general inquiries****Contact****Name of organization / entity**

Mazandaran University of Medical Sciences

Full name of responsible person

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Position

Professor

Latest degree

Specialist

Other areas of specialty/work

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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?****Person responsible for scientific inquiries****Contact****Name of organization / entity**

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Position

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Person responsible for updating data

Contact

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Latest degree
Specialist
Other areas of specialty/work
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Complex, Mazandaran University of Medical Sciences,
Faculty of Pharmacy
City
Sari
Province

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be 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

Undecided - It is not yet known if there will be 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