Clinical Trial Protocol
Iranian Registry of Clinical Trials

28 May 2026

Effects of dexmedetomidine on serum level of inflammatory factors in septic shock ICU patients

Protocol summary

Study aim
The effect of dexmedetomidine on the blood level of inflammatory markers in patients with septic shock

Design
Participants will be randomly assigned to two groups of intervention and control with 24 members using block randomization with block sizes of 4. Randomization will be done using the software randomization option in Excel. The randomization process is performed by the study methodology consultant and clinical researchers are not aware of the randomization process.

Settings and conduct
The intervention group, will receive a dose of 0.6 µg/kg/h dexmedetomidine for 12 hours.The dexmedetomidine vials contain 100 mcg of medicine which should be diluted and will reach the concentration of 4 mic/mL. Normal saline infusion of 6 ml/kg/h is infused in the control group instead of dexmedetomidine for 12 hours. The present study is double-blind so that patients and the final evaluator will be unaware of how the intervention and control group is allocated.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Septic shock over 18 years old Exclusion criteria: Receiving 10 micrograms per minute of norepinephrine or higher Heart blocks History of beta-blockers using

Intervention groups
The Intervention group receives Dexmedetomidine vial made by Hospira Co. with the brand name of Precedex, with a dose of 1 µg/kg for 10 minutes and then 0.2-2.5 µg/kg/h for 24 hours.The control group receives intravenous morphine manufactured by Darosh Pakhsh Co. with a dose of 0.5 to 5 mg/h and Midazolam intravenously from Daroo Pakhsh Co. with a dose of 0.5 to 5 mg/h

Main outcome variables
Main outcome variables include inflammatory factors including interleukin 1, interleukin 6, alpha TNF, the sedative effects of dexmedetomidine based on Richmond agitation-sedation scale, the study of changes in norepinephrine dose in two groups and the side effects of dexmedetomidine administration.

General information

Reason for update
Completion of the study

Acronym

IRCT registration information
IRCT registration number: **IRCT20181104041551N2**
Registration date: **2020-05-12, 1399/02/23**
Registration timing: **retrospective**

Last update: **2024-01-23, 1402/11/03**
Update count: **1**

Registration date
2020-05-12, 1399/02/23

Registrant information

Name
Fateme Heydari

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 11 3336 1700

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-08-23, 1397/06/01

Expected recruitment end date
2019-11-11, 1398/08/20

Actual recruitment start date
2018-08-25, 1397/06/03

Actual recruitment end date
2019-12-21, 1398/09/30
Trial completion date
2019-12-21, 1398/09/30

Scientific title
Effects of dexmedetomidine on serum level of inflammatory factors in septic shock ICU patients

Public title
Effects of dexmedetomidine on septic shock ICU patients
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Patients with septic shock over 18 years old
Exclusion criteria:
History of beta-blockers using Heart block or sick sinus syndrome Norepinephrine greater than 10 mcg/kg/min
Age
From **18 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Data analyser

Sample size
Target sample size: **48**
Actual sample size reached: **48**
Randomization (investigator's opinion)
Randomized
Randomization description
Participants will be randomly assigned to two groups of intervention and control with 33 members using block randomization with block sizes of 4. Randomization will be done using the software randomization option in Excel. The randomization process is performed by the study methodology consultant and clinical researchers are not aware of the randomization process.
Blinding (investigator's opinion)
Double blinded
Blinding description
After selecting the samples, none of the participant will be aware of randomization and allocation to groups. The data analyzer is from out of the study and all data will be provided in the form of coding to him. So, the present study is double-blinded.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Mazandaran University of Medical Sciences
Street address
Vice chancellor for research, Mazandaran University of Medical Sciences, Moallem Square, Sari, Iran
City
Sari
Province
Mazandaran
Postal code
4815733971
Approval date
2019-02-20, 1397/12/01
Ethics committee reference number
IR.MAZUMS.IMAMHOSPITAL.REC.1397.101

Health conditions studied

1

Description of health condition studied
Septic shock
ICD-10 code
R65.21
ICD-10 code description
Severe sepsis with septic shock

Primary outcomes

1

Description
Serum level of Inflammatory factor IL-1
Timepoint
Before the use of dexmedetomidine and after 24 hours
Method of measurement
ELISA test

2

Description
Serum level of Inflammatory factor IL-6
Timepoint
Before the use of dexmedetomidine and after 24 hours
Method of measurement
ELISA test

3

Description
Serum level of Inflammatory factor TNF-a
Timepoint
Before the use of dexmedetomidine and after 24 hours
Method of measurement
ELISA test

Secondary outcomes

1

Description
Investigation of the sedative effects of dexmedetomidine
Timepoint
Baseline and after 24 hours
Method of measurement
Richmond agitation-sedation scale

2

Description
changing norepinephrine dose of
Timepoint
Baseline and after 24 hours
Method of measurement
Clinical observation

3

Description
changing in Sofa score
Timepoint
Baseline and after 24 hours
Method of measurement
checklist

Intervention groups

1

Description
The Intervention group receives Dexmedetomidine vial made by Hospira Co. with the brand name of Precedex, with a dose of 1 µg/kg for 10 minutes and then 0.2-2.5 µg/kg/h for 24 hours.
Category
Treatment - Drugs

2

Description
Control group: The control group receives intravenous morphine manufactured by Darosh Pakhsh Co. with a dose of 0.5 to 5 mg/h and Midazolam intravenously from Daroo Pakhsh Co. with a dose of 0.5 to 5 mg/h
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Hospital
Full name of responsible person
Mehi Mokhlesian
Street address
Imam Hospital, Amir Mzandarani Blvd.
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f.heydari@mazums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Mazandaran University of Medical Sciences
Full name of responsible person
Dr. Majid Saeidi, Vice chancellor for research, Mazandaran University of Medical Sciences
Street address
Vice chancellor for research, Mazandaran University of Medical Sciences, Moallem square, Sari
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4817844718
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Email
majsaeedi@yahoo.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Mazandaran 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
Mazandaran University of Medical Sciences
Full name of responsible person
Dr. Fatemeh Heydari
Position
Assistant Professo

Latest degree
Subspecialist
Other areas of specialty/work
Anesthesiology
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Person responsible for updating data

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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
Yes - There is a plan to make this available
Statistical Analysis Plan
Not applicable
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
Not applicable
Title and more details about the data/document
All data can be shared
When the data will become available and for how long
Starting from April 2020
To whom data/document is available
People working in academic institutions
Under which criteria data/document could be used
Everyone
From where data/document is obtainable
Email to f.heydari@mazums.ac.ir
What processes are involved for a request to access data/document
Send email
Comments