Clinical Trial Protocol
Iranian Registry of Clinical Trials

27 May 2026

Comparison of the effect of statin and placebo on the development of sepsis and organ dysfunction in ICU patients.

Protocol summary

Study aim
The aim of this study is evaluating the effect of statin on the development of sepsis and organ dysfunction in patients with sepsis in the ICU.

Design
This prospective double-blind clinical trial will be performed on 36 patients with sepsis hospitalized in ICU. In this study patients will randomly be divided into two groups of 18 participants.

Settings and conduct
This is a prospective, double-blind clinical trial (participants and researchers are not aware of the information gathering and evaluation process). This study is conducted on patients with sepsis in the context of urinary tract infections or respiratory infections admitted to ICU at Vali Asr Hospital in Arak. Patients will be screened for vital signs, APACHE II Score, ESR and CRP levels, and the state of the tests, and then with regard to the objectives of the plan.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Age over 18 years; Sepsis in the context of pneumonia and urinary tract infections. Non-inclusion criteria: The patient has previously been treated with statin; The patient was previously afflicted with organ failure; Patients in whom a history of statin use in the past is not available.

Intervention groups
Patients in the intervention group receive Atorvastatin 40 mg oral tablet, daily for one month. Patients in the control group are given placebo for one month.

Main outcome variables
The outcome variables include ESR; CRP; APACHE II; blood sugar; GCS; GFR; serum creatinine; AST; ALT; PT; PTT; INR; FIO2 to PaO2 ratio.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20180713040452N1**
Registration date: **2019-05-02, 1398/02/12**
Registration timing: **registered_while_recruiting**

Last update: **2019-05-02, 1398/02/12**
Update count: **0**

Registration date
2019-05-02, 1398/02/12

Registrant information

Name
Sahand Astaneh

Name of organization / entity

Country
Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-04-21, 1398/02/01

Expected recruitment end date
2019-06-20, 1398/03/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison of the effect of statin and placebo on the development of sepsis and organ dysfunction in ICU patients.

Public title
Effaect of Statin on Sepsis and organ dysfunction
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
Age over 18 years old Patient with sepsis in the context of pneumonia and urinary tract infections.
Exclusion criteria:
The patient has previously been treated with statin The patient was previously afflicted with organ failure Patients in whom a history of statin use in the past is not available
Age
From **18 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Investigator
- Outcome assessor

Sample size
Target sample size: **36**
Randomization (investigator's opinion)
Randomized
Randomization description
Patients are divided into Statin and placebo groups by simple randomization method and by table of random numbers.
Blinding (investigator's opinion)
Double blinded
Blinding description
Research method is double blind clinical trial. Researcher (The outcome evaluator) and participants are not informed on receiving the statin or the placebo. Clinical caregivers take drugs that are named A and B to the patients. Data analyzer and Data Saftey and Monitoring Committee are aware of the fact that the participants have received Statin or placebo.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Arak Medical University
Street address
No. 45, Alamolhoda street, Shahid Shiroodi street, Arak
City
Arak
Province
Markazi
Postal code
3819693345
Approval date
2018-01-03, 1396/10/13
Ethics committee reference number
IR.ARAKMU.REC.1396.266

Health conditions studied

1

Description of health condition studied
sepsis
ICD-10 code
A41.8
ICD-10 code description
Other specified sepsis

Primary outcomes

1

Description
Erythrocyte Sedimentation Rate
Timepoint
Measurement on days 0, 3, 7, 14
Method of measurement
This variable is measured by the laboratory.

2

Description
C-Reactive Protein
Timepoint
Measurement on days 0, 3, 7, 14
Method of measurement
This variable is measured by the laboratory.

3

Description
APACHE II score
Timepoint
Measurement on days 0, 3, 7, 14
Method of measurement
The point score is calculated from a patient's age and 12 routine physiological measurements: 1) PaCO2 or PaO2 (depending on FiO2) 2)Temperature 3)Mean arterial pressure 4)pH arterial 5)Heart rate 6)Respiratory rate 7)Sodium (serum) 8) Potassium (serum) 9)Creatinine 10)Hematocrit 11)White blood cell count 12)Glasgow Coma Scale

4

Description
Nervous system failure

Timepoint
daily
Method of measurement
Based on Glasgow Coma Scale

5

Description
Renal Failure
Timepoint
daily
Method of measurement
1) Increased creatinine by more than 0.5 units in 72 hours; 2) Increased creatinine by more than 1.5 units during treatment; 3) Reduced glomerular filtration rate by more than 20 percent during treatment.

6

Description
Hepatic failure
Timepoint
daily
Method of measurement
1) Increase in alanine transaminase and aspartate transaminase during treatment, 2) Increase of the international normalize ratio and prothrombin time and partial thromboplastin time during treatment.

7

Description
Pulmonary failure
Timepoint
daily
Method of measurement
1) The ratio of FIO2 to PaO2 is less than 2 to 250. 2) Increased need for ventilation support.

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Patients in this group receive Atorvastatin 40 mg oral tablet, produced by the Abidi Company, daily for one month.
Category
Treatment - Drugs

2

Description
Control group: Patients in this group receive B-complex vitamin oral tablet, produced by the Daroupakhsh Company daily for one month.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Valiasr hospital
Full name of responsible person
Sahand Astaneh
Street address
Valiasr hospital, Valiasr squar, Arak
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Arak University of Medical Sciences
Full name of responsible person
Dr. Alireza Kamali
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No. 45, Alamolhoda street, Shahid Shiroodi street, Arak
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Web page address
https://arakmu.ac.ir/fa
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Arak 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
Arak University of Medical Sciences
Full name of responsible person
Sahand Astaneh
Position
Medical student
Latest degree
A Level or less
Other areas of specialty/work
Medical Education
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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
No - There is not a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
No - There is not a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available