

Clinical Trial Protocol

Iranian Registry of Clinical Trials

22 Jul 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)

Phone

+98 86 3422 4253

Email address

s.astaneh@arakmu.ac.ir

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
 Effect 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 Safety 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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3813138631

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Web page address

<https://valiasrhos.arakmu.ac.ir/Portal/Home/Default.aspx>

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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Fax

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Web page address

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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

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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No 31, Hoorad building; Shoa Alley; Shariati Street,
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Person responsible for updating data**Contact****Name of organization / entity**

Arak University of Medical Sciences

Full name of responsible person

Sahand Astaneh

Position

Medical intern

Latest degree

A Level or less

Other areas of specialty/work

Medical Education

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Full name of responsible person

Sahand Astaneh

Position

Medical intern

Latest degree

A Level or less

Other areas of specialty/work

Medical Education

Street address

No 31, Hoorad building; Shoa Alley; Shariati Street,
Arak

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