

Clinical Trial Protocol

Iranian Registry of Clinical Trials

06 Jul 2026

Effect of co_administration of vitamins A and D on symptoms in patients with pneumosepsis: a randomized clinical trial

Protocol summary

Study aim

Clinical trial of effect of coadministration of vitamins A and D on symptoms in patients with pneumosepsis.

Design

Blocked randomized, double blind, clinical trial study, single center, controlled placebo, sample size 80 patients selected in 6 months and block randomized into four groups.

Settings and conduct

A randomized, double-blind (Patients will be unaware of the type of intervention, The analyzer will be unaware of the type of interventions) clinical trial study, single center, 80 Samples selected via patients with pneumosepsis referred to the Valiasr, Amiralмомenin, Amir Kabir and Khansari Hospitals of Arak in 6 months and block randomized into four groups.

Participants/Inclusion and exclusion criteria

Age greater than 18 years old; sepsis diagnosis and infection source. Non-inclusion criteria: Vitamin D intake during 7 days ago; History of parathyroid diseases; End stage renal disease (ESRD)

Intervention groups

First (intervention) group receive, 300000 unit vitamin D (1 milliliter), Intramuscular (IM) with 50000 unit vitamin A (1 milliliter), Intramuscular (IM) as a single dose. The second group (intervention) receive, 300000 unit vitamin D (1 milliliter), Intramuscular (IM) as a single dose. The third group (intervention) receive, 50000 unit vitamin A (1 milliliter), Intramuscular (IM) as a single dose. The fourth group (control) receive, 2 milliliter normal saline as placebo, single dose, intramuscularly.

Main outcome variables

Vital signs, arterial blood oxygen, WBC, Cr, ESR, CRP, Serum uric acid level, Serum urea level

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20130424013110N11**

Registration date: **2020-10-05, 1399/07/14**

Registration timing: **prospective**

Last update: **2020-10-05, 1399/07/14**

Update count: **0**

Registration date

2020-10-05, 1399/07/14

Registrant information

Name

Mehdi Harorani

Name of organization / entity

Arak University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-10-22, 1399/08/01

Expected recruitment end date

2021-03-21, 1400/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of co_administration of vitamins A and D on symptoms in patients with pneumosepsis: a randomized clinical trial

Public title

Effect of co_administration of vitamins A and D in patients with pneumosepsis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age 18 to 80 years old Patients satisfaction Confirmed pneumosepsis disease

Exclusion criteria:

Unwillingness to cooperate Using Vitamin D supplements before intervention in the last three months Pregnancy

Age

From **18 years** old to **80 years** old

Gender

Both

Phase

2-3

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study the randomization will be done using block randomization method. In order to allocate the patients randomly into Intervention and control groups, at first 10 blocks of size 8 with C and T letters (The letters indicate the intervention and control groups) are created. Then the blocks are randomly selected and arranged to obtain a sequential combination of 80 letters. Each letter will be placed in a sealed packet according to the obtained sequence.

Blinding (investigator's opinion)

Double blinded

Blinding description

patients will be unaware of the type of intervention. The analyzer will be unaware of the type of interventions. Therefore, the trial will be run as double blind.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Arak University of Medical Sciences

Street address

Vice Chancellery For Research And Technology;
University campus; Basij square; Arak

City

Arak

Province

Markazi

Postal code

38481-76941

Approval date

2020-08-02, 1399/05/12

Ethics committee reference number

IR.ARAKMU.REC.1399.180

Health conditions studied

1

Description of health condition studied

Pneumosepsis

ICD-10 code

A41

ICD-10 code description

Other sepsis

Primary outcomes

1

Description

Measuring systolic and diastolic blood pressure

Timepoint

Before and every 6 hours after the intervention

Method of measurement

Digital pressure indicator gauge

2

Description

Pulse rate

Timepoint

Before and every 6 hours after the intervention

Method of measurement

Radial Pulse

3

Description

Respiratory rate

Timepoint

Before and every 6 hours after the intervention

Method of measurement

Observation chest in a minute

4

Description

Temperatures

Timepoint

Before and every 6 hours after the intervention

Method of measurement

Thermometer

5

Description

Measuring arterial oxygen percentage

Timepoint

Before and every 6 hours after the intervention

Method of measurement

Pulse oximetry device

6

Description

WBC

Timepoint

Before and 24, 48 and 72 hours after the intervention

Method of measurement

Cell blood count test

7

Description

ESR

Timepoint

Before and 24, 48 and 72 hours after the intervention

Method of measurement

Based on Lab data

8

Description

CRP

Timepoint

Before and 24, 48 and 72 hours after the intervention

Method of measurement

Based on Lab data

9

Description

Cr

Timepoint

Before and 24, 48 and 72 hours after the intervention

Method of measurement

Based on Lab data

10

Description

Serum uric acid level

Timepoint

Before and 24, 48 and 72 hours after the intervention

Method of measurement

Based on Lab data

11

Description

Serum urea level

Timepoint

Before and 24, 48 and 72 hours after the intervention

Method of measurement

Based on Lab data

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: First (intervention) group receive, 300000 unit vitamin D (1 milliliter), Intramuscular (IM) with 50000 unit vitamin A (1 milliliter), Intramuscular (IM) as a single dose.

Category

Treatment - Drugs

2

Description

Intervention group: The second group (intervention) receive, 300000 unit vitamin D (1 milliliter), Intramuscular (IM) as a single dose.

Category

Treatment - Drugs

3

Description

Intervention group: The third group (intervention) receive, 50000 unit vitamin A (1 milliliter), Intramuscular (IM) as a single dose.

Category

Treatment - Drugs

4

Description

Control group: The fourth group (control) receive, 2 milliliter normal saline as placebo, single dose, intramuscularly.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Valiasr Hospital Arak

Full name of responsible person

Dr Abolfazl Jokar

Street address

Valiasr Hospital, Valiasr Square, Arak, Iran

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Email

2

Recruitment center

Name of recruitment center

Amir Kabir Hospital

Full name of responsible person

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3

Recruitment center

Name of recruitment center

khansary Hospital

Full name of responsible person

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4

Recruitment center

Name of recruitment center

Amiralmomenin hospital

Full name of responsible person

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

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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

elham niyasti

Position

Resident in training; Emergency Medicine

Latest degree

Medical doctor

Other areas of specialty/work

Emergency Medicine

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Person responsible for scientific inquiries

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Person responsible for updating data

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Name of organization / entity
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Position

Faculty, Emergency medicine specialist
Latest degree
Specialist
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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

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