Clinical Trial Protocol
Iranian Registry of Clinical Trials

05 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, Amiralmomenin, 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)

Phone
+98 86 3417 3505

Email address
m.harorany@umsha.ac.ir

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
City
Arak
Province
Markazi
Postal code
3814957558
Phone
+98 86 3222 2003
Email

dr.a.jokar@gmail.com

2

Recruitment center

Name of recruitment center
Amir Kabir Hospital

Full name of responsible person
Dr Abolfazl Jokar

Street address
Amir Kabir Hospital, Basij Square, Arak, Iran

City
Arak

Province
Markazi

Postal code
3814957558

Phone
+98 86 3313 4717

Email
dr.a.jokar@gmail.com

3

Recruitment center

Name of recruitment center
khansary Hospital

Full name of responsible person
Dr Abolfazl Jokar

Street address
Daneshgah Avenue

City
Arak

Province
Markazi

Postal code
38149 - 75585

Phone
+98 86 3367 5001

Email
dr.a.jokar@gmail.com

4

Recruitment center

Name of recruitment center
Amiralmomenin hospital

Full name of responsible person
Dr Abolfazl Jokar

Street address
Amiralmomenin hospital, Sardasht, Arak, Iran

City
Arak

Province
Markazi

Postal code
3848176941

Phone
+98 86 3417 3601

Email
dr.a.jokar@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Arak University of Medical Sciences

Full name of responsible person
Dr Alireza Kamali

Street address
Vice Chancellery For Research And Education, Pardis Site Of University Of Medical Sciences, Basij Sq, Arak

City
Arak

Province
Markazi

Postal code
3848176341

Phone
+98 86 3417 3503

Email
research@arakmu.ac.ir

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

Street address
Valiasr Hospital, Valiasr Square, Arak

City
Arak

Province
Markazi

Postal code
3814957558

Phone
+98 86 3222 2003
Email
dr.a.jokar@gmail.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Arak University of Medical Sciences
Full name of responsible person
Dr Abolfazl Jokar
Position
Faculty, Emergency medicine specialist
Latest degree
Specialist
Other areas of specialty/work
Emergency Medicine
Street address
Valiasr Hospital, Valiasr Square, Arak
City
Arak
Province
Markazi
Postal code
3848176341
Phone
+98 86 3222 2003
Email
dr.a.jokar@gmail.com

Person responsible for updating data

Contact
Name of organization / entity
Arak University of Medical Sciences
Full name of responsible person
Dr Abolfazl Jokar
Position
Faculty, Emergency medicine specialist
Latest degree
Specialist
Other areas of specialty/work
Emergency Medicine
Street address
Valiasr Hospital, Valiasr Square, Arak
City
Arak
Province
Markazi
Postal code
3814957558
Phone
+98 86 3222 2003
Email
dr.a.jokar@gmail.com

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