

Clinical Trial Protocol

Iranian Registry of Clinical Trials

05 Jul 2026

Effect of co_administration of vitamins A and D on inflammatory cytokines of TNF-alfa and Intl-17 in patients with pneumosepsis: a randomized clinical trial

Protocol summary

Study aim

Clinical trial of effect of coadministration of vitamins A and D on inflammatory cytokines of TNF-alfa and Intl-17 in patients with pneumosepsis.

Design

Blocked randomized, double blind, clinical trial study, single center, controlled placebo, sample size 44 patients selected in 3 months and block randomized into two 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, 44 Samples selected via patients with pneumosepsis referred to the e Valiasr Hospital of Arak in 3 months and block randomized into two groups.

Participants/Inclusion and exclusion criteria

Inclusion 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. Second (control) group receive, 2 milliliter normal saline as placebo, single dose, intramuscularly.

Main outcome variables

Serum level of Vitamin A; Vitamin D; Interleukin17 and cytokine of TNF-alfa

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20130424013110N6**

Registration date: **2019-08-22, 1398/05/31**

Registration timing: **prospective**

Last update: **2019-08-22, 1398/05/31**

Update count: **0**

Registration date

2019-08-22, 1398/05/31

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

2019-09-01, 1398/06/10

Expected recruitment end date

2020-02-20, 1398/12/01

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 inflammatory cytokines of TNF-alfa and Intl-17 in patients with pneumosepsis: a randomized clinical trial

Public title

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

Purpose

Diagnostic

Inclusion/Exclusion criteria

Inclusion criteria:

Age 18 to 80 years old Patients satisfaction Hospitalized for at least 3 days

Exclusion criteria:

Unwillingness to cooperate Not using Vitamin D supplements before intervention In the last three months Pregnancy

Age

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

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Data analyser

Sample size

Target sample size: **44**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study the randomization will be done using blocking method. In order to allocate the patients randomly into two groups of treatment and control, at first 11 blocks of 4 with C and T letters (The letters indicate the intervention and control groups) are created in each 2 patients are belonged to the intervention group and 2 patients are belonged to the control group). Then the blocks are randomly selected and arranged to obtain a sequential combination of 11 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

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 Education, Pardis Site Of University Of Medical Sciences, Basij Sq, Arak

City

Arak

Province

Markazi

Postal code

38481-76941

Approval date

2019-04-07, 1398/01/18

Ethics committee reference number

IR.ARAKMU.REC.1398.006

Health conditions studied

1

Description of health condition studied

Pneumosepsis

ICD-10 code

A41

ICD-10 code description

Other sepsis

Primary outcomes

1

Description

cytokine of TNF-alfa

Timepoint

Before and 72 hours after the intervention.

Method of measurement

ELISA Kit

2

Description

Interleukin 17

Timepoint

Before and 72 hours after the intervention.

Method of measurement

ELISA Kit

3

Description

serum Vitamin D level

Timepoint

Before and 72 hours after the intervention.

Method of measurement

mg/dl

4

Description

serum Vitamin A level

Timepoint

Before and 72 hours after the intervention.

Method of measurement

mg/dl

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**

Control group: Second (control) group 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

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

Dr Abolfazl Jokar

Position

هیات علمی، متخصص طب اورژانس

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 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

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Province

Markazi

Postal code

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Phone

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dr.a.jokar@gmail.com

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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

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