Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Effect of co_administration of vitamins A and D compared to placebo on the level of regulatory T cells in pneumosepsis patients: a randomized clinical trial

Protocol summary

Study aim
The aim of the present study is to determine the combined effect of vitamin A and D on the level of regulatory T cells in pneumosepsis patients.

Design
Block randomized, double blind, clinical trial study, single center, controlled with placebo, sample size of 44 patients selected in 3 months and allocated into two groups through block randomization.

Settings and conduct
A randomized, double-blind (Patients and 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. Exclusion criteria: Vitamin D intake during three months 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
level of regulatory T cells

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20130424013110N10**
Registration date: **2020-07-06, 1399/04/16**
Registration timing: **registered_while_recruiting**
Last update: **2020-07-06, 1399/04/16**
Update count: **0**

Registration date
2020-07-06, 1399/04/16

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
2020-07-05, 1399/04/15

Expected recruitment end date
2021-01-04, 1399/10/15

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 compared to placebo on the level of regulatory T cells in pneumosepsis patients: 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 Hospitalized for at least 3 days 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
- Data analyser

Sample size
Target sample size: **44**
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 two groups of treatment and control, at first 11 blocks of size 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 44 letters. Each letter will be placed in a sealed packet according to the obtained sequence.
Blinding (investigator's opinion)
Double blinded
Blinding description
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. Therefore, 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 Technology; University campus; Basij square; Arak
City
Arak
Province
Markazi
Postal code
38481-76941
Approval date
2020-06-10, 1399/03/21
Ethics committee reference number
IR.ARAKMU.REC.1399.073

Health conditions studied

1

Description of health condition studied
Pneumosepsis
ICD-10 code
A41
ICD-10 code description
Other sepsis

Primary outcomes

1

Description
Regulatory T Cells frequency
Timepoint
Before and 72 hours after the intervention.
Method of measurement
Frequency of desired cells using Flow Cytometry Technique

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,
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 Technology; University campus; Basij square
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 Atefeh Pooyandeh
Position
Resident in training; Emergency Medicine
Latest degree
Medical doctor
Other areas of specialty/work
Emergency Medicine
Street address
Valiasr Hospital, Valiasr square, Shahid Shirodi street
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 Atefeh Pooyandeh

Position
Resident of emergency medicine

Latest degree
Medical doctor

Other areas of specialty/work
Emergency Medicine

Street address
Valiasr Hospital, Valiasr square, Shahid Shirodi street

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