Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Clinical trial of comparison of vitamin D and placebo on serum level of inflammatory and anti-inflammatory cytokines in patients with sepsis

Protocol summary

Summary

Objectives: Clinical trial of comparison of vitamin D and placebo on serum level of inflammatory and anti-inflammatory cytokines in patients with sepsis Design: Blocked randomized, double blind, clinical trial study, Single center, controlled placebo, Sample size 160 patients selected in 3 months and block randomized into two groups. Inclusion criteria: Age greater than 18 years old; sepsis diagnosis and infection source. Exclusion criteria: Calcium level greater than or equal to 10 mg/dl; Vitamin D intake during 7 days ago; History of parathyroid diseases; End stage renal disease (ESRD) Interventions: First (intervention) group receive, 300000 unit vitamin D (1 milliliter), Intramuscular (IM) as a single dose. Second (control) group receive, 1 milliliter normal saline as placebo, single dose, intramuscularly. Main outcome measures: Serum level of Ca, Vitamin D, Interleukin10 and tumor necrosis factor alpha will be checked 3 months after injection. Also, Duration of hospitalization in different wards and mortality rate will be recorded.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016090823552N8**
Registration date: **2016-10-05, 1395/07/14**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2016-10-05, 1395/07/14

Registrant information

Name

Abolfazl Jokar

Name of organization / entity

Arak University of Medical Sceinces

Country

Iran (Islamic Republic of)

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Email address

dr.a.jokar@gmail.com

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research,Arak University of Medical Sciences

Expected recruitment start date

2015-12-22, 1394/10/01

Expected recruitment end date

2016-06-21, 1395/04/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Clinical trial of comparison of vitamin D and placebo on serum level of inflammatory and anti-inflammatory cytokines in patients with sepsis

Public title

The effect of vitamin D on patients with Sepsis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Age greater than 18 years old; Sepsis diagnosis and infection source; Patients satisfaction Exclusion criteria: Calcium level greater than or equal to 10 mg/dl; Vitamin D intake during 7 days ago; History of parathyroid diseases; Metabolic bone disease; Sarcoidosis; End stage renal disease (ESRD); Impending

death; Pregnancy.

Age

From **18 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **160**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

In this study the randomization was conducted with block randomization method

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Arak University of Medical Sciences

Street address

Arak University Of Medical Science, Basij Square, Arak

City

Arak

Postal code

Approval date

2010-09-23, 1389/07/01

Ethics committee reference number

IR.ARAKMU.REC.1394.235

Health conditions studied

1

Description of health condition studied

Sepsis

ICD-10 code

A41.9

ICD-10 code description

Sepsis, unspecified

Primary outcomes

1

Description

Serum Ca level

Timepoint

3 months after injection

Method of measurement

mg/dl

2

Description

serum Vitamin D level

Timepoint

3 months after injection

Method of measurement

mg/dl

3

Description

Tumor necrosis factor alpha

Timepoint

3 months after injection

Method of measurement

ELISA

4

Description

Interleukin 10

Timepoint

3 months after injection

Method of measurement

ELISA

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group : These patients will received 1 milliliter vitamin D (300000 IU) (institut Pasteur.Tehran .Iran) , single dose, Intramuscularly.

Category

Treatment - Drugs

2

Description

Control group : These patients will received 1 ml intramuscular, single dose of normal saline as placebo.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center
Vali-e-Asr hospital

Full name of responsible person
Abolfazl Jokar

Street address
Vali-e-Asr hospital, Vali-e-Asr square, Arak,Iran

City
Arak

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Arak University of Medical Sciences, Vice Chancellor for Research

Full name of responsible person
Dr. Mohammad Rafiee

Street address
Arak University of Medical Sciences, Basij Square, Arak, Iran

City
Arak

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, Vice Chancellor for Research

Proportion provided by this source
100

Public or private sector
empty

Domestic or foreign origin
empty

Category of foreign source of funding
empty

Country of origin

Type of organization providing the funding
empty

Person responsible for general inquiries

Contact

Name of organization / entity
Vali-e-Asr hospital

Full name of responsible person
Dr Abolfazl Jokar

Position
Emergency medicine specialist

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty

Study Protocol
empty

Statistical Analysis Plan
empty

Informed Consent Form
empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty