

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Randomized clinical trial comparison of vitamin D and placebo in urosepsis

Protocol summary

Summary

Objectives: Comparison of vitamin D and placebo in urosepsis Design: Blocked randomized, double blind, Single center, controlled placebo, Sample size 100 patients Inclusion criteria: Age between 18 to 70 years old; sepsis diagnosis with urinary tract infection. 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: In first (intervention) group, 300000 unit vitamin D (1 milliliter), Intramuscular(IM) as a single dose, added to urosepsis standard treatment .In second (control) group, 1 milliliter normal saline as placebo, IM, added to urosepsis standard treatment. Main outcome measures: Vital signs monitored every 6 hours until 72 hours and CBC, ESR, CRP, Creatinine, Urea and Uric Acid measured at baseline, 24, 48 and 72 hours after injection and serum level of Calcium, phosphorus and vitamin D measured at baseline and 72 hours after injection.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016030223552N7**
Registration date: **2016-10-15, 1395/07/24**
Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2016-10-15, 1395/07/24

Registrant information

Name

Abolfazl Jokar

Name of organization / entity

Arak University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 86 3313 2134

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

2016-04-20, 1395/02/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Randomized clinical trial comparison of vitamin D and placebo in urosepsis

Public title

The effect of vitamin D on urosepsis

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: Age between 18 to 70 years old; Sepsis diagnosis with urinary tract infection; 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 to **70 years** old

Gender

Both

Phase

2

Groups that have been masked*No information***Sample size**Target sample size: **100****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, Markazi

City

Arak

Postal code

00

Approval date

2015-12-16, 1394/09/25

Ethics committee reference number

ir.arakmu.rec.1394.237

Health conditions studied**1****Description of health condition studied**

sepsis

ICD-10 code

A41.5

ICD-10 code description

Sepsis due to other Gram-negative organisms

Primary outcomes**1****Description**

White blood cell

Timepoint

every 24 hours to 72 hours

Method of measurement

Number per microliter

2**Description**

Temperature

Timepoint

every 6 hours to 72 hours

Method of measurement

Thermometer

3**Description**

ESR

Timepoint

Every 24 hours to 72 hours

Method of measurement

mm per hour

4**Description**

Creatinine

Timepoint

Every 24 hours to 72 hours

Method of measurement

mg /dl

5**Description**

CRP

Timepoint

Every 24 hours to 72 hours

Method of measurement

mg/dl

Secondary outcomes**1****Description**

Systolic blood pressure

Timepoint

Every 6 hours to 72 hours

Method of measurement

Sphygmomanometer

2**Description**

Diastolic blood pressure

Timepoint

Every 6 hours to 72 hours

Method of measurement

Sphygmomanometer

3

Description

Heart rate

Timepoint

Every 6 hours to 72 hours

Method of measurement

Pulse per minute

4

Description

Respiratory rate

Timepoint

Every 6 hours to 72 hours

Method of measurement

Respiration per minute

5

Description

Blood urea nitrogen (BUN)

Timepoint

Every 6 hours to 72 hours

Method of measurement

mg / dl

6

Description

Calcium

Timepoint

At baseline and 72 hour after injection

Method of measurement

mg / dl

7

Description

Phosphorus

Timepoint

At baseline and 72 hour after injection

Method of measurement

mg / dl

8

Description

Vitamin D

Timepoint

At baseline and 72 hour after injection

Method of measurement

mg / dl

9

Description

Uric acid

Timepoint

Every 24 hours to 72 hours

Method of measurement

mg/dl

Intervention groups

1

Description

Intervention group : These patients receive 300000 IU vitamin D (institut Pasteur.Tehran .Iran) ,with 1 cc volume, Intramuscular

Category

Treatment - Drugs

2

Description

Control group : These patients receive 1 ml intramuscular normal saline as placebo.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Vali-e-Asr hospital

Full name of responsible person

Dr Abolfazl Jokar

Street address

Vali-e-Asr hospital, Vali-e-Asr square, Arak.

City

Aarak

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research,Arak University of Medical Sciences

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

Vice chancellor for research,Arak University of Medical Sciences

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**Street address**

Vali-e-Asr hospital, Vali-e-Asr square, Arak, Markazi

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Vali-e-Asr hospital

Full name of responsible person

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Position

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Position

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Postal code

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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