

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Jun 2026

Effect of calcitriol supplementation on infectious biomarkers including Procalcitonin and Presepsin with positive systemic inflammatory response

Protocol summary

Study aim

The effect of prescribing an active form of vitamin D in the form of calcitriol on the markers of infection including procalcitonin and presepsin in patients with positive systemic inflammatory responses that are candidates for intravenous antibiotics due to suspected infection according to the ICU practitioner.

Design

open labeled pilot study

Settings and conduct

positive SIRS patients of imam hussein hospital will be divided into intervention and control group and will be evaluated.

Participants/Inclusion and exclusion criteria

including criteria Individuals over the age of 18 years who are clinically considered positive for SIRS (within the first 48 hours of diagnosis), based on the following criteria (if 2 of the 4 parameters are positive), and according to the ICU, the antibiotic team started for them Be: 1) The temperature is above 38 degrees or below 36 degrees Celsius 2) Heart rate above 90 beats per minute 3) The number of respiration above 20 or arterial carbon dioxide below 32 mm Hg 4) The number of white blood cells > 12000 or < 4000 Exit criteria 1) Serum calcium ≥ 10 mg / dl or serum phosphate ≥ 6 mg / dl in the last 48 hours 2) Receiving vitamin D supplements with doses of more than 1000 units per day or calcitriol with each dose in the last week 3) history of diseases including primary parathyroidism, sarcoidosis, metabolic bone disease, and renal failure in the last stage 4) Pregnancy and lactation 5) Length of hospital stay in the ICU below 48 hours

Intervention groups

Patients were divided into two intervention and control groups. In the intervention group, patients received 1 microgram of venous calcitriol for 3 consecutive days but did not receive calcitriol in the control group.

Main outcome variables

level of serum procalcitonin and presepsin

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180522039777N1**

Registration date: **2018-10-07, 1397/07/15**

Registration timing: **retrospective**

Last update: **2018-10-07, 1397/07/15**

Update count: **0**

Registration date

2018-10-07, 1397/07/15

Registrant information

Name

Farnoosh Masbough

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 7743 3195

Email address

farnoosh.masbough@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-11-22, 1396/09/01

Expected recruitment end date

2018-04-21, 1397/02/01

Actual recruitment start date

2017-12-06, 1396/09/15

Actual recruitment end date

2018-07-11, 1397/04/20

Trial completion date

2018-07-11, 1397/04/20

Scientific title

Effect of calcitriol supplementation on infectious biomarkers including Procalcitonin and Presepsin with positive systemic inflammatory response

Public title

Effect of calcitriol in infection

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

all positive SIRS patients greater than or equal to 18 years with suspicion to infection that antibiotics have been started for them

Exclusion criteria:**Age**

From **18 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **30**

Actual sample size reached: **29**

Randomization (investigator's opinion)

Randomized

Randomization description

random numbers table

Blinding (investigator's opinion)

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of shahid beheshti University of Medical Sciences

Street address

Vali asr Ave.down from the crossroads niayesh

City

Tehran

Province

Tehran

Postal code

1991953381

Approval date

2017-11-06, 1396/08/15

Ethics committee reference number

IR.SBMU.PHNM.1396.885

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

positive systemic inflammatory response

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

improved in procalcitonin marker

Timepoint

Marker measurements at day 0, 3 and 5 after calcitriol injection

Method of measurement

Reduce symptoms of inflammation

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group:

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Emam hossein hospital

Full name of responsible person

farnoosh masbough

Street address

Emam Hossein Hosp. - Madani St. - Tehran - Iran

City

tehran

Province

Tehran

Postal code

1617763141

Phone

+98 21 7759 0148

Email

info@ehmc.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

tahereh shams

Street address

velenjak street, shahid chamran high way

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Province

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1985717443

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Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Shahid Beheshti 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**

Shahid Beheshti University of Medical Sciences

Full name of responsible person

mohammad sistanizad

Position

assistant professor, clinical pharmacy specialist

Latest degree

Specialist

Other areas of specialty/work

Medical Pharmacy

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Person responsible for scientific inquiries

Contact**Name of organization / entity**

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Full name of responsible person

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Position

assistant of professor, clinical pharmacy specialist

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Person responsible for updating data

Contact**Name of organization / entity**

Shahid Beheshti University of Medical Sciences

Full name of responsible person

farnoosh masbough

Position

دانشجوی داروسازی

Latest degree

Medical doctor

Other areas of specialty/work

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1766685491

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Email

farnoosh.masbough@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

No more information

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available