

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

Comparison of the effectiveness of vitamin c supplementation on procalcitonin biomarker in community acquired pneumonia

Protocol summary

Study aim

The effect of vitamin c supplementation on procalcitonin biomarker in community acquired pneumonia

Design

Parallel, placebo, double blind, randomized clinical trial

Settings and conduct

The statistical population included patients referred to infectious unit of shahid beheshti hospital in Kashan. Patients, researcher and doctors were unaware of the medications or placebo interventions. Patients and medications were coded by someone who did not intervene in the study. Intervention group: This group received one vitamin C 1000 mg EFF tab daily and other medications for treating pneumonia for 10 days. Control group: This group received one vitamin C placebo 1000 mg EFF tab daily and other medications for treating pneumonia for 10 days. serum procalcitonin was measured at the beginning of patient's entrance and at the end of the study(after 10 days) .

Participants/Inclusion and exclusion criteria

Inclusion criteria: Diagnosis of community acquired pneumonia by physician based on clinical symptoms, chest x-ray.patients's, history and lab test results. Obtaining informed consent from the patients. Patients older than 18 years old in both gender Exclusion criteria: Pregnancy or lactation .Any hepatic or kidney failure. Taking any chemothrapy medications and NSAIDs. Taking antibiotics for other infectious disease at the same time

Intervention groups

Intervention group: This group received one vitamin C 1000 mg EFF tab daily and other medications for treating pneumonia for 10 days. Control group: This group received one vitamin c placebo 1000 mg EFF tab daily and other medications for treating pneumonia for 10 days. Serum procalcitonin was measured and checked at the beginning of patient's entrance and at the end of the study(after 10 days) .

Main outcome variables

Serum level of procalcitonin in day 1 and 10 did not show any significant difference between drug and placebo groups.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20150706023084N3**

Registration date: **2019-10-11, 1398/07/19**

Registration timing: **retrospective**

Last update: **2019-10-11, 1398/07/19**

Update count: **0**

Registration date

2019-10-11, 1398/07/19

Registrant information

Name

MARYAM SHIEHMORTEZA

Name of organization / entity

AZAD UNIVERSITY PHARMACEUTICAL SCIENCES

Country

Iran (Islamic Republic of)

Phone

+98 212640056

Email address

shiehmorteza@iaups.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-03-06, 1396/12/15

Expected recruitment end date

2019-01-21, 1397/11/01

Actual recruitment start date

2018-03-16, 1396/12/25

Actual recruitment end date

2019-04-15, 1398/01/26

Trial completion date

2019-04-24, 1398/02/04

Scientific title

Comparison of the effectiveness of vitamin c supplementation on procalcitonin biomarker in community acquired pneumonia

Public title

Effect of vitamin c supplementation on procalcitonin biomarker in community acquired pneumonia

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

Diagnosis of community acquired pneumonia by physician based on clinical symptoms, chest x-ray, patients's history and lab test results Obtaining informed consent from the patients Patients older than 18 years old in both gender.

Exclusion criteria:

Pregnancy or lactation Any hepatic or kidney failure Taking any chemotherapy medications and NSAIDs Taking antibiotics for other infectious disease at the same time

Age

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

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator

Sample size

Target sample size: **40**

More than 1 sample in each individual

Number of samples in each individual: **2**

Serum of procalcitonin

Actual sample size reached: **35**

More than 1 sample in each individual

Actual sample size in each individual: **2**

Serum of procalcitonin

Randomization (investigator's opinion)

Randomized

Randomization description

Simple randomization Random-number table

Blinding (investigator's opinion)

Double blinded

Blinding description

All patients who had the necessary conditions to enter the study were assigned randomly into two groups of drugs and placebo. Patients, researcher and doctors were unaware of the medications or placebo interventions. Patients and medications were coded by someone who did not intervene in the study.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics committee of department of pharmaceutical tehran islamic azad university of medical science.

Street address

Dr shariati street, Khaghani street, Tehran islamic azad university of medical science

City

Tehran

Province

Tehran

Postal code

1916893813

Approval date

2018-03-03, 1396/12/12

Ethics committee reference number

IR.IAU.PS.REC.1396.220

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

Community acquired pneumonia

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

Procalcitonin(PCT) is produced in c-cells of thyroid gland as a prohormone of calcitonin. PCT has emerged as promising marker for the diagnosis of infections, because higher level of pct is found in bacterial infections than in viral infections and non specific inflammatory disease. Serum is used for measure of level of procalcitonin.

Timepoint

Serum level of procalcitonin was measured at the beginning and at the end of the study(after 10 days).

Method of measurement

The serum pct level was measured by VIDAS Biomerieux and pct kit, prepared by ELFA.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: This group received one vitamin C 1000 mg EFF tab daily and other medications for treating pneumonia for 10 days. Serum procalcitonin was measured and checked at the beginning of patient's entrance and at the end of the study(after 10 days).

Category

Treatment - Drugs

2

Description

Control group: This group received one vitamin C placebo 1000 mg EFF tab daily and other medications for treating pneumonia for 10 days. Serum procalcitonin was measured and checked at the beginning of patient's entrance and at the end of the study(after 10 days).

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid beheshti hospital in kashan

Full name of responsible person

Dr.Mansoreh Momen Heravi

Street address

Ghotb ravandi street, Shahid beheshti hospital

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Kashan

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Isfahan

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beheshtihospital@kaums.ac.ir

Web page address

<http://beheshti.kaums.ac.ir/>

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Islamic Azad University

Full name of responsible person

Dr Farshad Hashemian

Street address

Dr shariati street, Khaghani street, Tehran islamic azad university of medical science

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

No

Title of funding source

Student

Proportion provided by this source

100

Public or private sector

Private

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Persons

Person responsible for general inquiries

Contact

Name of organization / entity

Islamic Azad University

Full name of responsible person

Mahsa Nikzad

Position

Student

Latest degree

Medical doctor

Other areas of specialty/work

Medical Pharmacy

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Person responsible for scientific inquiries

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Full name of responsible person

Mahsa Nikzad

Position

Student

Latest degree

Medical doctor

Other areas of specialty/work

Medical Pharmacy

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Person responsible for updating data

Contact

Name of organization / entity

Islamic Azad University

Full name of responsible person

Maryam Shieh Morteza

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

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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