

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 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-rey.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

##### City

Kashan

##### Province

Isfahan

##### Postal code

87159/81151

##### Phone

+98 31 5554 0026

##### Fax

+98 31 5554 8900

##### Email

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

#### City

Tehran

#### Province

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#### Phone

+98 21 2200 6660

#### Fax

+98 21 2260 0714

#### Email

info@iau.ac.ir

#### Web page address

<http://iaups.iautmu.ac.ir/fa>

#### 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

##### Street address

Sattarkhan stree, North habibollah street, North gholami street, No 5

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##### Province

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## Person responsible for scientific 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 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**

Clinical pharmacy

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**Email**

shiehorteza@iaups.ac.ir

## 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