

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Study the effect of Zinc on the increase Immune responses after Pneumococcal vaccination (Penumovax) in elderly

Protocol summary

Summary

The objective of this study is to survey the influence of zinc sulfate on increasing levels of antibody production following pneumococcal vaccination in people older than 65 years. Participants were assigned into following groups. The patients in the intervention group received single dose of pneumococcal vaccine 23 valent (Merck Company, Germany) injected into the deltoid muscle, intramuscularly, as well as Zinc sulfate capsules (Alhavy company, Iran) 200 mg daily, PO for a month. The patients in the control group received single dose of pneumococcal vaccine 23 valent (Merck Company, Germany) injected into the deltoid muscle, intramuscularly, as well as placebo (capsules filled with sugar) for a month. Specific pneumococcal antibody levels were measured before and one month after vaccination by ELISA method.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138905094479N1**
Registration date: **2010-11-09, 1389/08/18**
Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2010-11-09, 1389/08/18

Registrant information

Name

Seyed Mohamad Karimivafa

Name of organization / entity

Kermanshah University Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 83 1726 3527

Email address

drvafa@kums.ac.ir

Recruitment status

Recruitment complete

Funding source

Kermanshah University of Medical Sciences

Expected recruitment start date

2010-03-21, 1389/01/01

Expected recruitment end date

2010-06-22, 1389/04/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Study the effect of Zinc on the increase Immune responses after Pneumococcal vaccination (Penumovax) in elderly

Public title

Study the effect of Zinc on the increase Immune responses after Pneumococcal vaccination (Penumovax) in elderly

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: age 65 years of age, no lung infection, full consent to participate in the study, no allergic or any other systemic diseases, Pneumococcal vaccination the past three years

Age

From **65 years** old to **120 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 120

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Double blinded

Blinding description**Placebo**

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**Ethics Committee of Kermanshah University of
Medical Sciences**Street address**Kermanshah University Medical Sciences, Shahid
Beheshti Street**City**

Kermanshah

Postal code

6718647657

Approval date

2010-06-15, 1389/03/25

Ethics committee reference number

89026

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

Immunity for pneumococcal vaccine

ICD-10 code

J13

ICD-10 code description

Pneumonia due to Streptococcus pneumoniae

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

Immunity against pneumococcal vaccine

Timepoint

One Month

Method of measurement

ELIZA

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

Edema and Indurations due to vaccine

Timepoint

One Month

Method of measurement

Observation

Intervention groups**1****Description**pneumococcal vaccine 23 valent (Merck Company,
Germany) injected into the deltoid muscle,
intramuscularly, as well as Zinc sulfate capsules (Alhavy
company, Iran) 200 mg daily, PO for a month**Category**

Prevention

2**Description**pneumococcal vaccine 23 valent (Merck Company,
Germany) injected into the deltoid muscle,
intramuscularly, as well as placebo (capsules filled with
sugar) for a month**Category**

Prevention

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

Kermanshah University Medical Sciences

Full name of responsible person

Sayed Mohamad Karimi Vafa

Street address

Against Sepah Bank, West Motahary Street

City

Kermanshah

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Kermanshah University Medical Sciences

Full name of responsible person

Sayed Mohamad Karimi Vafa

Street address

Infection Ward, Emam Reza Hospital

City

Kermanshah

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Kermanshah University 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

Kermanshah University of Medical Sciences

Full name of responsible person

Sayed Mohamad Karimi Vafa

Position

Resident

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

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Full name of responsible person

Faizolah Mansoury

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Person responsible for updating data

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Position

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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