

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Evaluation of selenium effect on antibody titers of seasonal influenza vaccination in adult older than 40 years in, Imam Reza hospital, Kermanshah

Protocol summary

Summary

This objective of this randomized, double blind clinical trials is to evaluate the effect of selenium on antibody titers of seasonal influenza vaccination in adult older than 40 years. In this study, 116 persons who have antibody titers against H1N1, H3N2, and Inf-B less than 1:40 are randomly assigned into intervention or control group. Trivalent influenza vaccine (VAXIGRIP) will be injected in deltoid muscle for the both groups. The intervention group will receive influenza vaccine and selenium selenate (200 micro/ gm / daily/ for 30 days) while the control group will receive influenza vaccine and placebo (sugar, one capsule /daily /for 30 days). After 30 days, antibody titers will be measured and compared between groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201010184959N1**

Registration date: **2010-11-12, 1389/08/21**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2010-11-12, 1389/08/21

Registrant information

Name

Sohrab Heidari

Name of organization / entity

Kermanshah University Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 83 1426 3264

Email address

a-heidary@kums.ac.ir

Recruitment status

Recruitment complete

Funding source

Kermanshah University of Medical Sciences

Expected recruitment start date

2010-10-23, 1389/08/01

Expected recruitment end date

2010-11-21, 1389/08/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of selenium effect on antibody titers of seasonal influenza vaccination in adult older than 40 years in, Imam Reza hospital, Kermanshah

Public title

Evaluation of selenium effect on antibody titers of seasonal influenza vaccination in adults older than 40 years

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: Age more than 40 years old, serum antibody less than 1:40, absence of flu-like syndrome

Age

From **50 years** old to **100 years** old

Gender

Both

Phase

N/A

Groups that have been masked
No information

Sample size
Target sample size: 116

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 of Medical Sciences, Shahid Beheshti Street

City
Kermanshah

Postal code
6714415333

Approval date
2010-09-06, 1389/06/15

Ethics committee reference number
7/420/6212/پ

Health conditions studied

1

Description of health condition studied
Influenza

ICD-10 code
J09, J18

ICD-10 code description
Influenza and pneumonia

Primary outcomes

1

Description
Immunity for Influenza Viruses

Timepoint
One month after Vaccination

Method of measurement
With Hemagglutination and Inhibition Method

Secondary outcomes

1

Description
Adverse effect of vaccination

Timepoint
One Month

Method of measurement
Observation

Intervention groups

1

Description
An injection of Trivalent influenza vaccine (VAXIGRIP) in deltoid muscle and selenium selenate (200 micro gm/ daily/ for 30 days)

Category
Prevention

2

Description
Trivalent influenza vaccine (VAXIGRIP) will be injected in deltoid muscle and placebo daily/ for 30 days.

Category
Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center
Infection Ward, Emam Reza Hospital

Full name of responsible person
Dr. Sohrab Heidari

Street address
Infection Ward, Emam Reza Hospital

City
Kermanshah

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Kermanshah University of Medical Sciences

Full name of responsible person
Dr. Alireza Janbakhsh

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 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
Kermanshah University of Medical Sciences
Full name of responsible person
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Other areas of specialty/work
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Person responsible for scientific inquiries

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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