

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Aug 2026

The comparison of antibody response to standard intramuscular and half dose intradermal influenza vaccine in patient on long term hemodialysis in Shiraz in 1388

Protocol summary

Summary

This study was performed to compare antibody responses following influenza vaccination in two ways (standard dose intramuscular and half dose intradermal) in hemodialysis patients. 110 chronic hemodialysis patients without a history of recent influenza vaccination, hospitalization, or recent flu and taking immune suppressants were chosen. The patients randomly assigned to be vaccinated using standard intramuscular dose (0.5ml), in the deltoid muscle in the control group or half dose intradermal (0.25ml), in the forearm area in the intervention group. Titers of serum antibodies before vaccination was measured a month and three months later by ELISA. The rate of influenza infection was also compared during 6 months after vaccination.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201009044683N1**

Registration date: **2010-10-25, 1389/08/03**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2010-10-25, 1389/08/03

Registrant information

Name

Samira Saeian

Name of organization / entity

Shiraz University of Medical Science&Health Services

Country

Iran (Islamic Republic of)

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+98 71 1647 4316

Email address

saeians@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Shiraz University of Medical Sciences & Health Services

Expected recruitment start date

2009-10-23, 1388/08/01

Expected recruitment end date

2009-11-11, 1388/08/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The comparison of antibody response to standard intramuscular and half dose intradermal influenza vaccine in patient on long term hemodialysis in Shiraz in 1388

Public title

Administration of influenza vaccine

Purpose

Health service research

Inclusion/Exclusion criteria

Inclusion criteria: Patients under chronic hemodialysis

Exclusion criteria: history of flu infection in a month, history of flu vaccination in 1388, hospitalization in last month, taking immune suppressants, hemodialysis less than two times a week

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **110**

Randomization (investigator's opinion)

Randomized

Randomization description

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

Shiraz University of Medical Sciences & Health Services

Street address

Shiraz, Zand boulevard

City

Shiraz

Postal code

Approval date

2010-08-23, 1389/06/01

Ethics committee reference number

ct-89-5205

Health conditions studied

1

Description of health condition studied

Influenza vaccination

ICD-10 code

Z25.1

ICD-10 code description

need for immunization against influenza

Primary outcomes

1

Description

Anti influenza antibody titer

Timepoint

Before vaccination, one month after vaccination, three months after vaccination

Method of measurement

ELISA

Secondary outcomes

1

Description

Influenza infection

Timepoint

Six months after vaccination

Method of measurement

History & Physical exam

Intervention groups

1

Description

Intervention group: intradermal administration of seasonal influenza vaccine, 0.25ml, in forearm area in October 2009

Category

Prevention

2

Description

Control group: intramuscular administration of seasonal influenza vaccine, 0.5ml, in deltoid muscle in October 2009

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Sadra hemodialysis center

Full name of responsible person

Street address

City

Shiraz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences & Health Services

Full name of responsible person

Mohammad Hossein Dabbaghmanesh

Street address

Internal medicine department, Namazi hospital

City

Shiraz

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Shiraz University of Medical Sciences & Health Services

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

Shiraz University of Medical Sciences & Health Services

Full name of responsible person

Samira Saeian

Position

Internal medicine assistant

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