Clinical Trial Protocol
Iranian Registry of Clinical Trials

21 Jul 2026

Comparing intramuscular and intradermal injection of trivalent influenza vaccine, and topical imiquimod use before intradermal vaccination, on the post-vaccination immunogenicity, in patients on maintenance hemodialysis: A randomized clinical trial

Protocol summary

Summary

The goal of this multicenteric study is to compare the immunogenicity of trivalent influenza vaccine, when it is administered via intradermal and intramuscular injections and also evaluating the effect of Imiquimod cream on respose improvement, when it is used before intradermal injection. In this randomized controlled trial, 120 adult individuals above 18 years old, known to have end stage renal disease and need maintenance hemodialysis (i.e. at least 2 times a week for more than one month) without history of influenza or other viral diseases and live viral vaccination in recent 4 weeks entered the study. They had not received influenza vaccine in the last 6 months. The patients who had history of hypersensitivity reaction to egg and components of influenza vaccine were excluded. They were randomly assigned into three groups, by means of random table of digits, with equal 40 persons in each group. For the first group (INT-I), 250mg Imiquimod 5% cream was rubbed on deltoid region of right arm, and after 15 minutes, 0.25cc of trivalent influenza vaccine was injected intradermal. The ones in the second group (INT-A) received 0.25cc trivalent influenza vaccine via intradermal route after rubbing 250 mg aqueous cream in the same region with the same prior interval. For the third group (IM-A), 0.5 cc trivalent influenza vaccine was injected intramuscular after using 250 mg aqueous topical cream on the same area. The applied inactivated trivalent influenza vaccines in this study, complied with the WHO recommendations for northern hemisphere and European Union decision for the 2015/2016 season, and contained seasonal split-virus of theses strains: -A/California/07/2009 (H1N1)pdm09–like strain, -Influenza A/Switzerland/9715293/2013 (H3N2)–like strain and -Influenza B/Phuket/3073/2013. They contained 15 µg hemagglutinin of each strain per 0.5 cc of the vaccine. For comparing the increase in antibody titers, two blood samples obtained: the first immediately before and the second 14-21 days after vaccination. Serum antibody titers against two influenza strains: A (H1N1) and B, will be measured by hemagglutination-inhibition (HI) assay testing. The comparison between INT-A and IM-A groups (primary outcome measure) and also between INT-A and INT-I groups (secondary outcome measure) will be done.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015101724575N1**
Registration date: **2017-06-04, 1396/03/14**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2017-06-04, 1396/03/14

Registrant information

Name

Zahra Doosti

Name of organization / entity

Infectious Diseases Research Center, Shahid Beheshti University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

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Recruitment status

Recruitment complete

Funding source

Investigator

Expected recruitment start date
2016-02-04, 1394/11/15
Expected recruitment end date
2016-03-05, 1394/12/15
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparing intramuscular and intradermal injection of trivalent influenza vaccine, and topical imiquimod use before intradermal vaccination, on the post-vaccination immunogenicity, in patients on maintenance hemodialysis: A randomized clinical trial

Public title
Comparing different methods of trivalent influenza vaccination on the post-vaccination immunogenicity in patients on maintenance hemodialysis
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria: Individuals more than 18 years old who are known to have end stage renal disease and need routine dialysis (i.e. at least 2 times a week for more than one month). Exclusion criteria: History of influenza or other viral diseases and also live viral vaccination in recent 4 weeks; History of influenza vaccination in prior 6 months; Prior history of hypersensitivity to egg, components of influenza vaccine; Documented primary or secondary immunosuppression especially impaired cellular and humoral immunity.
Age
From **18 years** old to **100 years** old
Gender
Both

Phase
3
Groups that have been masked
No information
Sample size
Target sample size: **120**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Used
Assignment
Parallel
Other design features
Randomization was done by means of random table of digits; Patients were informed about the goals of study, to the extent that further assignment and randomization would not be interfered, and they were aware that participation was completely facultative. The volunteers then asked to sign the written consent before initiation of study.

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Shahid Beheshti University of Medical Sciences
Street address
Shahid Beheshti University of Medical Sciences, Shahid A'arabi street, Yaman street, Chamran highway, Tehran, Iran
City
Tehran
Postal code
Approval date
2016-02-02, 1394/11/13
Ethics committee reference number
IR.SBMU.SM.REC.1394.173

Health conditions studied

1

Description of health condition studied
Need for immunization against influenza
ICD-10 code
Z25.1
ICD-10 code description
Need for immunization against influenza

Primary outcomes

1

Description
Comparing the immunogenicity against influenza vaccine via intradermal and intramuscular routes.
Timepoint
Obtaining blood samples for antibody titration, before and 14 to 21 days after vaccination
Method of measurement
Antibody titration within the sera obtained before and after vaccination, by hemagglutination inhibition assay test.

Secondary outcomes

1

Description
The effect of imiquimod pretreatment before intradermal influenza vaccination on immunogenicity of vaccine

Timepoint
Antibody titration within blood samples obtained before and 14 to 21 days after vaccination

Method of measurement
Antibody titration within the sera obtained before and after vaccination, by hemagglutination inhibition assay test.

Intervention groups

1

Description
The first group (Intervention): 250mg Imiquimod 5% cream (Aldara) was rubbed on deltoid region of right arm, and after 15 minutes, 0.25cc of trivalent influenza vaccine was injected intradermal. The applied inactivated trivalent influenza vaccines in this study, complied with the WHO recommendations for northern hemisphere and European Union decision for the 2015/2016 season, and contained seasonal split-virus of theses strains: -A/California/07/2009 (H1N1)pdm09–like strain, -Influenza A/Switzerland/9715293/2013 (H3N2)–like strain and -Influenza B/Phuket/3073/2013. They contained 15 µg hemagglutinin of each strain per 0.5 cc of the vaccine.

Category
Treatment - Drugs

2

Description
The second group (Intervention/Control): received 0.25cc trivalent influenza vaccine via intradermal route after rubbing 250 mg aqueous cream in the same region with the same prior interval. The applied inactivated trivalent influenza vaccines in this study, complied with the WHO recommendations for northern hemisphere and European Union decision for the 2015/2016 season, and contained seasonal split-virus of theses strains: -A/California/07/2009 (H1N1)pdm09–like strain, -Influenza A/Switzerland/9715293/2013 (H3N2)–like strain and -Influenza B/Phuket/3073/2013. They contained 15 µg hemagglutinin of each strain per 0.5 cc of the vaccine.

Category
Placebo

3

Description
The third group (control): 0.5 cc trivalent influenza vaccine was injected intramuscular after using 250 mg aqueous topical cream on the same area. The applied inactivated trivalent influenza vaccines in this study, complied with the WHO recommendations for northern hemisphere and European Union decision for the 2015/2016 season, and contained seasonal split-virus of theses strains: -A/California/07/2009 (H1N1)pdm09–like strain, -Influenza A/Switzerland/9715293/2013 (H3N2)–like strain and -Influenza B/Phuket/3073/2013. They contained 15 µg hemagglutinin of each strain per 0.5 cc of the vaccine.

Category
Prevention

Recruitment centers

1

Recruitment center
Name of recruitment center
Dialysis ward of Shargh Medical Center
Full name of responsible person
Mrs.Danyali
Street address
Mesgar Abad, Jaddeh-ye-Mesgar Abad, Tehran, Iran
City
Tehran

2

Recruitment center
Name of recruitment center
Dialysis ward of Loghman-Hakim Teaching Hospital
Full name of responsible person
Mrs.Shakeri
Street address
Kamali street, Karegar-e-jonoubi street, Tehran, Iran
City
Tehran

3

Recruitment center
Name of recruitment center
Dialysis ward of Imam-Hossein Teaching Hospital
Full name of responsible person
Mrs.Komijani
Street address
Shahid Madani street, Tehran, Iran
City
Tehran

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for research, Shahid Beheshti University of Medical Sciences
Full name of responsible person
Ms.Saraabi
Street address
Vice chancellor for research, Shahid Beheshti University of Medical Sciences, Shahid A'arabi street, Yaman street, Chamran highway, Tehran, Iran
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Tehran

Grant name
-

Grant code / Reference number
-

Is the source of funding the same sponsor

organization/entity?
Yes
Title of funding source
Vice chancellor for research, Shahid Beheshti 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
Infectious Diseases and Tropical Medicine Research Center, Shahid Beheshti University of Medical Sci
Full name of responsible person
Zahra Doosti
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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