

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 May 2026

Comparison of safety and efficacy of standard dose and doubling of seasonal flu vaccine in patients receiving kidney transplantation in Imam Khomeini Hospital, 2021

Protocol summary

Study aim

Comparison of safety and efficacy of standard and double dose of seasonal influenza vaccine in patients underwent kidney transplantation

Design

This is the open-labeled study and people receiving kidney transplants (60 people) were divided into two groups: 1) the group receiving the standard dose of influenza vaccine (n=30) and 2) people receiving the dose of influenza vaccine (n=30). This study examines patients in the first phase of a clinical trial.

Settings and conduct

Participants are divided into two groups: recipients of standard dose of influenza vaccine and double dose of this vaccine. Serum samples were collected before and four weeks after injection and the amount of antibody produced was measured by micro neutralization assay.

Participants/Inclusion and exclusion criteria

Participants: Adult kidney transplant recipients at least three months have passed since the transplant. No entry: People with autoimmune diseases who are taking immunosuppressive drugs and people who recently underwent kidney transplantation.

Intervention groups

Intervention group 1) Group receiving standard dose of seasonal flu vaccine Intervention group 2) Group receiving double dose of seasonal flu vaccine

Main outcome variables

Influenza A and B's antibody

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210121050096N1**
Registration date: **2021-11-21, 1400/08/30**

Registration timing: **retrospective**

Last update: **2021-11-21, 1400/08/30**

Update count: **0**

Registration date

2021-11-21, 1400/08/30

Registrant information

Name

Mohsen Meidani

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 21 6658 1598

Email address

meidani@med.mui.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-09-06, 1400/06/15

Expected recruitment end date

2021-11-21, 1400/08/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of safety and efficacy of standard dose and doubling of seasonal flu vaccine in patients receiving kidney transplantation in Imam Khomeini Hospital, 2021

Public title

Evaluating the effectiveness of influenza vaccine in

kidney transplant recipients in Imam Khomeini Hospital

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

At least 18 years old At least three months have passed since their transplant.

Exclusion criteria:

Treatment for acute transplantation reject Acute febrile illness in the last two weeks Previous life-threatening reactions to vaccine products (such as Guillain-Barré syndrome) Patients with any autoimmune disease receiving corticosteroids or immunosuppressive drugs. Patients who have recently underwent kidney transplant.

Age

From **18 years** old

Gender

Both

Phase

1-2

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Blocking is commonly used to balance the number of samples assigned to each of the study groups and helps to ensure that the number of samples assigned to each of the study groups is equal. The tool for generating random block sequences in this study is Random allocation software. In this clinical trial of 60 people (including 30 people in the double dose group of influenza vaccine and 30 people in the single dose group of influenza vaccine) 10 blocks of 6 will be formed. In each block, 6 people including 3 participants will be assigned to the Double dose group and 3 participants to the Single dose group.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Tehran University of Medical Sciences

Street address

Qarib Ave., Imam Khomeini hospital complex

City

Tehran

Province

Tehran

Postal code

۱۴۱۹۷۳۳۱۴۱

Approval date

2021-04-21, 1400/02/01

Ethics committee reference number

IR.TUMS.MEDICINE.REC.1400.081

Health conditions studied

1

Description of health condition studied

Kidney Transplant Recipients

ICD-10 code

T86.19

ICD-10 code description

Other complication of kidney transplant

Primary outcomes

1

Description

Influenza A's Antibody

Timepoint

Before intervention and four weeks after vaccination

Method of measurement

Evaluating the influenzas' antibodies by serology

2

Description

Influenza B's Antibody

Timepoint

Before intervention and four weeks after vaccination

Method of measurement

Evaluating the influenzas' antibodies by serology

Secondary outcomes

1

Description

Fever

Timepoint

3 days after injection

Method of measurement

Clinical Examination

2

Description

Getting the flu

Timepoint

3 days after injection

Method of measurement

Evaluation of the patient's clinical symptoms

3

Description

Existence of pain at the injection site

Timepoint

3 days after injection

Method of measurement

Clinical Examination

4

Description

Redness at the injection site

Timepoint

3 days after injection

Method of measurement

Clinical Examination

5

Description

Systemic side effects

Timepoint

3 days after injection

Method of measurement

Clinical Examination

Intervention groups

1

Description

Intervention group: Receiving a standard dose of seasonal influenzae tetravalent vaccine (15µg of Hemophilus Influenza Antigen). This 2021-2022 vaccine is inactivated and is made by the Dutch company Abbott. The brand name of this vaccine is Inluvac. The viral strains of this vaccine include the following: A/Victoria/2570/2019 (H1N1)pdm09-like strainA/Cambodia/e0826360/2020 (H3N2)-like strainB/Washington/02/2019-like strainB/Phuket/3073/2013-like strain

Category

Treatment - Drugs

2

Description

Intervention group: Receiving a double dose of seasonal influenzae tetravalent vaccine (30µg of Hemophilus Influenza Antigen). This 2021-2022 vaccine is inactivated and is made by the Dutch company Abbott. The brand name of this vaccine is Inluvac. The viral strains of this vaccine include the following: A/Victoria/2570/2019 (H1N1)pdm09-like strainA/Cambodia/e0826360/2020 (H3N2)-like strainB/Washington/02/2019-like strainB/Phuket/3073/2013-like strain

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center**Name of recruitment center**

Imam Khomeini Hospital Complex

Full name of responsible person

Mohsen Meidani

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Imam Khomeini Hospital Complex, Qarib Ave.,

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Imamhospital@tums.ac.ir

Sponsors / Funding sources

1

Sponsor**Name of organization / entity**

Tehran University of Medical Sciences

Full name of responsible person

Dr. Akbar Fotouhi

Street address

Vice Chancellor of Research, Tehran University of Medical Sciences, Qods Ave., Keshavarz Blvd. ,

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Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Tehran University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

SeyedAhmad SeyedAlinaghi

Position

Associate Professor

Latest degree

Ph.D.

Other areas of specialty/work

Clinical Epidemiology

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Person responsible for scientific inquiries

Contact

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Position

Associate Professor

Latest degree

Specialist

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Elnaz Karimian

Position

Resident

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Medical doctor

Other areas of specialty/work

Infectious diseases

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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