Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 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)

Phone
+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 Influvac. 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 Influvac. 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
Street address
Imam Khomeini Hospital Complex۹ Qarib Ave.,
City
Tehran
Province
Tehran
Postal code
۱۴۱۹۷۳۳۱۴۱
Phone
+98 21 6190
Email
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. ,
City
Tehran
Province
Tehran
Postal code
0000000000
Phone
+98 21 8163 3686
Email
vcr@tums.ac.ir
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

Street address
Iranian Research Center for HIV/AIDS, Imam Khomeini Hospital Complex, Qarib Ave.

City
Tehran

Province
Tehran

Postal code
۱۴۱۹۷۳۳۱۴۱

Phone
+98 21 6658 1583

Email
s_a_alinaghi@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Tehran University of Medical Sciences

Full name of responsible person
Mohsen Meidani

Position
Associate Professor

Latest degree
Specialist

Other areas of specialty/work
Infectious diseases

Street address
Infectious Disease Department, Imam Khomeini Hospital Complex, Qarib Ave.

City
Tehran

Province
Tehran

Postal code
۱۴۱۹۷۳۳۱۴۱

Phone
+98 21 6658 1598

Email
meidani@med.mui.ir

Person responsible for updating data

Contact

Name of organization / entity
Tehran University of Medical Sciences

Full name of responsible person
Elnaz Karimian

Position
Resident

Latest degree
Medical doctor

Other areas of specialty/work
Infectious diseases

Street address
Iranian Research Center for HIV/AIDS, Imam Khomeini Hospital Complex, Qarib Ave.

City
Tehran

Province
Tehran

Postal code
۱۴۱۹۷۳۳۱۴۱

Phone
+98 21 2275 3488

Email
karimianelnaz@yahoo.com

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