

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 May 2026

Evaluation of the immunogenicity and safety of quadrivalent flu vaccine (Fluguard) manufactured by Nivad pharmed Salamat, in comparison with seasonal flu vaccine Vaxigrip, as a reference product made by Sanofi, France in healthy volunteers aged 18 to 49 years, study Clinical phase 3 random, double-blind, double-arm, parallel, active control, non-inferiority

Protocol summary

Study aim

Immunogenicity determination of fluguard vaccine in comparison with vaxigrip in an inferiority study design

Design

This study is a phase 3 study with active control group, randomized (with a ratio of 1: 1), two-arm, parallel, double-blind and with non-inferiority design

Settings and conduct

This study was performed on healthy volunteers aged 18 to 49 years in Tehran in 1399. The place of study is located in Tehran and Enghelab Street. On the day of screening, blood samples (for routine test and baseline Antibody titer) and Covid test will be taken from the volunteers. Two days later, the volunteer will return to receive the vaccine, then 28 days later, a blood sample will be taken from the volunteer again to measure the antibodies titer after injection. Vaccines in both groups are in single-form envelopes and random codes are used to identify them, so the candidate will not be informed of the type of vaccine received.

Participants/Inclusion and exclusion criteria

1. Age between 18-49 2. Have general health 3. Sign informed consent 4. Be able to accompany with the visit programs and study process

Intervention groups

1. Pre-filled syringe of fluguard, quadrivalent vaccine, (manufactured by Nivad pharmed), 45µg HA/serotype/dose, intramuscular injection (Non-dominant hand deltoid muscle), 0.5 ml per visit 2. Pre-filled syringe of Vaxigrip, quadrivalent vaccine, (manufactured by Sanofi), 15µg HA/serotype/dose, intramuscular injection (Non-dominant hand deltoid muscle), 0.5 ml per visit

Main outcome variables

Ratio of antibody titer against hemagglutinin protein of

species A H1N1, A H3N2, B Yamagata, B Victoria with GMT scale after 28 days compared to the control group

General information

Reason for update

Increase and modify the sample size Add new Exclusion criteria

Acronym

IRCT registration information

IRCT registration number: **IRCT20200318046812N4**

Registration date: **2021-01-21, 1399/11/02**

Registration timing: **registered_while_recruiting**

Last update: **2021-01-23, 1399/11/04**

Update count: **1**

Registration date

2021-01-21, 1399/11/02

Registrant information

Name

Mostafa Ghanei

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 8860 0067

Email address

mghaneister@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-01-20, 1399/11/01

Expected recruitment end date

2021-03-19, 1399/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the immunogenicity and safety of quadrivalent flu vaccine (Fluguard) manufactured by Nivad pharmed Salamat, in comparison with seasonal flu vaccine Vaxigrip, as a reference product made by Sanofi, France in healthy volunteers aged 18 to 49 years, study Clinical phase 3 random, double-blind, double-arm, parallel, active control, non-inferiority

Public title

Evaluation of the immunogenicity and safety of quadrivalent seasonal flu vaccine and comparison with influenza vaccine named Vaxigrip

Purpose

Prevention

Inclusion/Exclusion criteria**Inclusion criteria:**

Age between 18-49 Have general health Sign informed consent Be able to accompany with the visit programs and study process

Exclusion criteria:

History of previous vaccinations against influenza strains used in injectable vaccines during the previous 6 months History of allergy to Vaxigrip Received another vaccine during this study Covid-19 infection (PCR confirmation) Diagnosis of any disease, receiving medication or vaccine within 30 days before enrollment Underlying disease or therapeutic intervention that may adversely affect the immune response Participate in other clinical studies Pregnancy, breastfeeding or pregnancy planning during the study period Any conditions that prevent the study volunteer from enrollment, due to PI opinion such as:

- Receiving immunomodulatory drugs or immunosuppressants
- Receiving immunoglobulins
- History of allergic reactions or Guillain-Barre syndrome
- Autoimmune diseases

A history of previous hospitalization with flu-like symptoms or a proven flu illness

Age

From **18 years** old to **49 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Data analyser

Sample size

Target sample size: **1369**

Randomization (investigator's opinion)

Randomized

Randomization description

Random sequencing of volunteers is done by sealedenvelope.com. Using random blocks each block size is 4 will be constructed for a total of 1150 volunteers (2: 1 ratio).

Blinding (investigator's opinion)

Double blinded

Blinding description

Due to the similarity of the control and test drug packages and also random codes are used to identify them, the candidates will not be informed about the type of vaccine they received. Also, according to the identity codes of each patient that is created at the beginning of the study, the study data will be provided anonymously to the study results analysis team. Thus, the study is blinded for the patient and the evaluator.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

National Research Ethics Committee

Street address

Tehran - Ghods Town (West) - Between South Flamek and Zarafshan, Iran TV Street - Central Headquarters of the Ministry of Health, Treatment and Medical Education, Block A, 13th floor

City

Tehran

Province

Tehran

Postal code

3848176941

Approval date

2021-01-12, 1399/10/23

Ethics committee reference number

IR.NREC.1399.004

Health conditions studied**1****Description of health condition studied**

seasonal flu vaccination

ICD-10 code

J09

ICD-10 code description

Influenza due to certain identified influenza viruses

Primary outcomes

1

Description

Ratio of antibody titer against hemagglutinin protein of species A H1N1 with GMT scale after 28 days compared to control group

Timepoint

Day zero and 28

Method of measurement

ELISA

2

Description

Ratio of antibody titer against hemagglutinin protein of species A H3N2 with GMT scale after 28 days compared to the control group

Timepoint

Day zero and 28

Method of measurement

ELISA

3

Description

Ratio of antibody titer against Yamagata species B hemagglutinin protein with GMT scale after 28 days compared to control group

Timepoint

Day zero and 28

Method of measurement

ELISA

4

Description

Ratio of antibody titer against Victoria B species hemagglutinin protein with GMT scale after 28 days compared to control group

Timepoint

Day zero and 28

Method of measurement

ELISA

Secondary outcomes

1

Description

Seroconversion rate against hemagglutinin protein species A H1N1 after 28 days

Timepoint

Day zero and 28

Method of measurement

ELISA

2

Description

Seroconversion rate against hemagglutinin protein species A H3N2 after 28 days

Timepoint

Day zero and 28

Method of measurement

ELISA

3

Description

Seroconversion rate against Yamagata species B hemagglutinin protein after 28 days

Timepoint

Day zero and 28

Method of measurement

ELISA

4

Description

Seroconversion rate against Victoria B species hemagglutinin protein after 28 days

Timepoint

Day zero and 28

Method of measurement

ELISA

Intervention groups

1

Description

Intervention group: Pre-filled syringe of Fluguard seasonal flu vaccine (manufactured by Nivad Pharmed Salamat) 45µg HA / serotype / dose, intramuscular injection (non-dominant hand deltoid muscle) of 0.5 ml at the first visit

Category

Prevention

2

Description

Control group: Pre-filled Vaxigrip Seasonal Influenza Vaccine Syringe (manufactured by Sanofi), 15µg HA / serotype / dose, intramuscular injection (non-dominant hand deltoid muscle) 0.5 ml at first visit

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Dr. Mohammad Hosseini Pharmacy

Full name of responsible person

Dr. Mostafa Ghanei

Street address

No. 36, Shahid Nazari St., Enqelab St., Enghelab St., Dr. Mohammad Hosseini Pharmacy, Second Floor

City

Tehran

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Tehran
Postal code
۱۱۵۷۹۴۳۰۸۸
Phone
+98 21 6648 0876
Email
nooshin185@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Nivad Pharmed Salamat Company
Full name of responsible person
Dr. Amirhossein Abdolghafari
Street address
No. 54, Sharif Innovation Station, Above Hassan
Hosseini Sq., Azadi St., Habibollah St., Nivad pharmed
Salamat Co.
City
Tehran
Province
Tehran
Postal code
1455714181
Phone
+98 21 9107 7022
Email
info.nivad@gmail.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Nivad Pharmed Salamat Company

Proportion provided by this source

100

Public or private sector

Private

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Industry

Person responsible for general inquiries

Contact

Name of organization / entity
Nivad pharmed Salamat Co.
Full name of responsible person
Dr. Setayesh Sadeghi
Position
Clinical pharmacist resident
Latest degree
Medical doctor

Other areas of specialty/work

Medical Pharmacy

Street address

No. 54, Sharif Innovation Station, Above Hassan
Hosseini Sq., Azadi St., Habibollah St., Nivad pharmed
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+98 21 9107 7022

Email

sadeghi.setayesh@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Nivad pharmed Salamat Co.

Full name of responsible person

Dr. Setayesh Sadeghi

Position

Clinical pharmacist resident

Latest degree

Medical doctor

Other areas of specialty/work

Medical Pharmacy

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Email

sadeghi.setayesh@gmail.com

Person responsible for updating data

Contact

Name of organization / entity

Nivad pharmed Salamat Co.

Full name of responsible person

Dr. Setayesh Sadeghi

Position

Clinical pharmacist resident

Latest degree

Medical doctor

Other areas of specialty/work

Medical Pharmacy

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Province

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Email

sadeghi.setayesh@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

Because of confidentiality

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available