Clinical Trial Protocol
Iranian Registry of Clinical Trials

04 Jun 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

Province
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Phone
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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
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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
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No. 54, Sharif Innovation Station, Above Hassan Hosseini Sq., Azadi St., Habibollah St., Nivad pharmed Salamat Co.
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Person responsible for scientific inquiries

Contact
Name of organization / entity
Nivad pharmed Salamat Co.
Full name of responsible person
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Position
Clinical pharmacist resident
Latest degree
Medical doctor
Other areas of specialty/work
Medical Pharmacy
Street address
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Person responsible for updating data

Contact
Name of organization / entity
Nivad pharmed Salamat Co.
Full name of responsible person
Dr. Setayesh Sadeghi
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Medical doctor
Other areas of specialty/work
Medical Pharmacy
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Salamat Co.

City

Tehran

Province

Tehran

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Phone

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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