Clinical Trial Protocol
Iranian Registry of Clinical Trials

05 Jun 2026

Safety evaluation of a quadrivalent recombinant influenza vaccine (serotypes of 2021/2022) manufactured by Nivad Pharmed Salamat, open label, single arm, in volunteers aged ≥ 18 years.

Protocol summary

Study aim
Accurate safety assessment of the quadrivalent seasonal flu vaccine (2021-2022), Fluguard in the population receiving the vaccine

Design
Open Label, single arm on 1000 participants

Settings and conduct
Participants will install the web application, after registering the information and checking the eligibility, they are given a special code and then the call center team contacts the person and injects them the vaccine. The volunteer is present at the study site for 30 minutes after the injection, so that in case of any adverse events after the injection, the necessary measures will be taken by the research team. To follow up on other events, the team will call the participant after 1 day, 4 days, 7 days, 14 days after the injection. On the other hand, blood samples are collected in a subgroup of 250 participants to evaluate the immunogenicity of pre-vaccination and 28 days post-vaccination.

Participants/Inclusion and exclusion criteria
Inclusion Criteria: Aged ≥ 18 years; Able to provide informed consent; Willing to comply with the study visits; Healthy subjects or patients with stable concomitant disease Exclusion Criteria: Subject is currently participating or is planning to participate in another trial; Females with confirmed pregnancy; planning on conceiving during the trial duration, and breastfeeding; Fever at the time of entry; Having an active infection with clinical signs of Covid-19; History of severe allergy to any type of vaccine; History of Guillain-Barré; Covid-19 vaccination at least 2 weeks before participation; receive Covid-19 vaccine for at least the next 2 weeks

Intervention groups
pre-filled syringe of Fluguard quadrivalent flu vaccine containing strains of 2021-2022, 45µg HA/ serotype/dose for intramuscular injection of 0.5 ml

Main outcome variables
Number of people with Solicited Adverse Drug Reactions in the first 7 days after injection (days 0-6)

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20201104049265N2**
Registration date: **2021-09-15, 1400/06/24**
Registration timing: **registered_while_recruiting**

Last update: **2021-09-15, 1400/06/24**
Update count: **0**

Registration date
2021-09-15, 1400/06/24

Registrant information

Name
Seyyedeh Maryam Afshani

Name of organization / entity
Arta Zist Pharmed

Country
Iran (Islamic Republic of)

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+98 21 8609 2503

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-09-15, 1400/06/24

Expected recruitment end date
2021-10-16, 1400/07/24

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Safety evaluation of a quadrivalent recombinant influenza vaccine (serotypes of 2021/2022) manufactured by Nivad Pharmed Salamat, open label, single arm, in volunteers aged ≥ 18 years.

Public title

Safety evaluation of quadrivalent recombinant influenza vaccine (serotypes of 2021/2022), open label, single arm, in volunteers aged ≥ 18 years.

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Aged ≥ 18 years Able to provide written informed consent Subject is willing to comply with the study visits Healthy subjects or patients with stable concomitant diseases (the underlying disease is controlled and there is no need for hospitalization)

Exclusion criteria:

Subject is currently participating or is planning to participate in another clinical trial in 1 month Females of childbearing age with confirmed or suspected pregnancy, those planning on conceiving during the trial duration and women who are breastfeeding Fever at the time of entry (temperature > 38 measured by remote thermometer) Having an active infection with clinical signs of Covid-19 such as fever or chills, cough, fatigue, headache, shortness of breath, sore throat, change in sense of smell or taste, or any other warning signs of infection within 72 hours before injection (If a person has already had the disease and has recovered, participation in the study is not prohibited.) History of severe allergy to any type of vaccine (anaphylactic shock) History of Guillain-Barré or other demyelinating diseases Covid-19 vaccination at least 2 weeks before participation Planning to receive Covid-19 vaccine for at least the next 2 weeks according to the national vaccination protocol

Age

From **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **1000**

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Other

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Iran National Committee for Ethics in Biomedical Research

Street address

Floor 13, Block A, Ministry of Health & Medical Education Headquarters, Between Zarafashan & South Falamak, Qods Town, Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1467664961

Approval date

2021-09-13, 1400/06/22

Ethics committee reference number

IR.NREC.1400.008

Health conditions studied

1

Description of health condition studied

Influenza due to certain identified influenza viruses

ICD-10 code

J09

ICD-10 code description

J09

Primary outcomes

1

Description

Number of participants with Solicited Local and Systemic Adverse Drug Reactions in the first 7 days after injection (days 0-6)

Timepoint

days 0-6

Method of measurement

number of participants

2

Description

Number of participants with Unsolicited Adverse Events in the first 7 days after injection (days 0-6)

Timepoint

days 0-6

Method of measurement
number of participants

3

Description
Number of participants with vasovagal syncope in the first 7 days after injection (day 0-6) based on VAERS
Timepoint
days 0-6
Method of measurement
number of participants

4

Description
Number of participants with fever (any, Grade 3, related) in the first 7 days after injection (days 0-6)
Timepoint
days 0-6
Method of measurement
number of participants

Secondary outcomes

1

Description
Unsolicited Adverse Events 7 to 14 days after vaccination
Timepoint
Days 7 to 14
Method of measurement
number of participants

2

Description
Number of participants with Adverse Events of Special Interest (AESIs) 42 days after injection
Timepoint
Day 42
Method of measurement
number of participants

3

Description
Number of participants with Medically Attended Adverse Events (MAEs) in 14 days after injection
Timepoint
days 0 to 14
Method of measurement
number of participants

4

Description
Number of participants with SAEs
Timepoint
Throughout the study
Method of measurement
number of participants

5

Description
Number of seroconverted subjects for Hemagglutination Inhibition Antibodies assay against 4 strains of influenza on day 28 after vaccination
Timepoint
day 28
Method of measurement
number of participants

Intervention groups

1

Description
Intervention group: pre-filled syringe of Fluguard quadrivalent flu vaccine containing strains of 2021-2022, 45µg HA/ serotype/dose for intramuscular injection of 0.5 ml
Category
Prevention

Recruitment centers

1

Recruitment center
Name of recruitment center
Amirabad Center
Full name of responsible person
Dr. Mostafa Ghanei
Street address
Number 86, 15th alley, north Kargar street
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
NIVAD Pharmed Salamat
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.
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Tehran

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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

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
Arta Zist Pharmed
Full name of responsible person
Dr. Setayesh Sadeghi
Position
Medical Department Manager
Latest degree
Specialist
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Person responsible for scientific inquiries

Contact

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Person responsible for updating data

Contact

Name of organization / entity
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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
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