

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 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, 45 μ g 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)

Phone

+98 21 8609 2503

Email address

m.afshani@artapharmed.com

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

City

Tehran

Province

Tehran

Postal code

1439763163

Phone

+98 21 8609 2503

Email

mghaneister@gmail.com

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.

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

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

Other areas of specialty/work
Medical Pharmacy

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West side of Sheikh Baha'i Square, Ryan Vanak Building, No. 18, 6th floor, Unit 603

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Person responsible for scientific inquiries

Contact

Name of organization / entity
Bagheiat-allah University of Medical Sciences

Full name of responsible person
Dr. Mostafa Ghanei

Position

Professor

Latest degree
Subspecialist

Other areas of specialty/work
Lung Specialist

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19945-581

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Person responsible for updating data

Contact

Name of organization / entity
Arta Zist Pharmed

Full name of responsible person
Dr. Seyyedeh Maryam Afshani

Position
سرپرست واحد مدیکال

Latest degree
Medical doctor

Other areas of specialty/work
Medical Pharmacy

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West side of Sheikh Baha'i Square, Ryan Vanak Building, No. 18, 6th floor, Unit 603

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Email
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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