

# 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 $\geq 18$ 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  $\geq 18$  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 $\mu$ 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  $\geq 18$  years.

**Public title**  
Safety evaluation of quadrivalent recombinant influenza vaccine (serotypes of 2021/2022), open label, single arm, in volunteers aged  $\geq 18$  years.

**Purpose**  
Prevention

**Inclusion/Exclusion criteria**  
**Inclusion criteria:**  
Aged  $\geq 18$  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

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

**City**  
Tehran

**Province**  
Tehran

**Postal code**  
1993873057

**Phone**  
+98 21 8609 2794

**Email**  
s.sadeghi@artapharmed.com

## 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

**Street address**  
Mollasadra Street

**City**  
Tehran

**Province**  
Tehran

**Postal code**  
19945-581

**Phone**  
+98 21 8860 0067

**Email**  
m.ghanei@bmsu.ac.ir

## 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 مديكال

**Latest degree**  
Medical doctor

**Other areas of specialty/work**  
Medical Pharmacy

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

**City**  
Tehran

**Province**  
Tehran

**Postal code**  
1993873057

**Phone**  
+98 21 8609 2794

**Email**  
m.afshani@artapharmed.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

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