Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Investigating the comparative preventive efficacy and safety of FluGaurd® (a 4-valent recombinant influenza vaccine, produced by Niwad-Pharmed-Salamat company, I.R.Iran), to Vaxigrip® (produced by Sanofi company, France) as the reference product in Healthy volunteers

Protocol summary

Study aim

Investigating the comparative preventive efficacy and safety of Flugaurd, to Vaxigrip as the reference product in Healthy volunteers

Design

This study is designed as a phase III, randomized, two-armed, double-blind, parallel, active controlled, and non-inferiority clinical trial in healthy volunteers.

Settings and conduct

Volunteers who are eligible to enter, will be enrolled. Administration will be done at the vaccination clinic of Baqiyatallah hospital.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: The age of the volunteer is between 18 and 49 years; The volunteer has general health; The volunteer or his/her legal guardian must have signed the informed consent form; The volunteer must be able to keep up with the monitoring programs. Exclusion Criteria:Have a history of previous vaccinations against influenza strains used in this vaccines; Have a history of allergy to Vaxigrip; History of chronic use immunosuppressive/modulator drugs in the last 6 months; History of any immune system disorders; History of chronic diseases; History of receiving immunoglobulins or other blood products 90 days before the vaccination; Pregnancy; Lactation.

Intervention groups

Intervention group: Pre-filled syringe of Flugaurd, 45µg HA/serotype/dose, intramuscular injection (at non-dominant hand deltoid muscle) in the amount of 0.5 ml in the first visit. Control group: Pre-filled syringe of Vaxigrip, 45µg HA/serotype/dose, intramuscular injection (at non-dominant hand deltoid muscle) in the amount of 0.5 ml in the first visit.

Main outcome variables

The ratio of antibody titer against hemagglutinin proteins type A H1N1، A H3N2، B Victoria، B Yamagata with GMT scale after 28 days compared to the control group; The difference in seroconversion rate against the A H1N1، A H3N2، B Victoria، B Yamagata hemagglutinin proteins after 28 days compared to the control group;

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20080901001165N61**
Registration date: **2020-06-12, 1399/03/23**
Registration timing: **prospective**

Last update: **2020-06-12, 1399/03/23**
Update count: **0**

Registration date

2020-06-12, 1399/03/23

Registrant information

Name

Yunes Panahi

Name of organization / entity

Baqiyatallah University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

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Email address

yunespanahi@bmsu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-08-22, 1399/06/01

Expected recruitment end date

2020-11-21, 1399/09/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the comparative preventive efficacy and safety of FluGaurd® (a 4-valent recombinant influenza vaccine, produced by Niwad-Pharmed-Salamat company, I.R.Iran), to Vaxigrip® (produced by Sanofi company, France) as the reference product in Healthy volunteers

Public title

Investigating the comparative preventive efficacy and safety of FluGaurd® (a 4-valent recombinant influenza vaccine, produced by Niwad-Pharmed-Salamat company, I.R.Iran), to Vaxigrip® (produced by Sanofi company, France) as the reference product in Healthy volunteers

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

The age of the volunteer is between 18 and 49 years. The volunteer has general health (through clinical examinations and medical records). The volunteer or his/her legal guardian must have signed the informed consent form. The volunteer must be able to keep up with the monitoring programs.

Exclusion criteria:

Have a history of previous vaccinations against influenza strains used in injectable vaccines; Have a history of allergy to Vaxigrip; History of chronic use (more than 14 days) immunosuppressive drugs in the last 6 months (in the case of corticosteroids, prednisolone (or its equivalents) in the amount of 0.5 mg per kg of volunteer weight per day. Topical or inhaled steroids usage are free.) History of any immune system disorders such as Guillain-Barré syndrome and other Masculoscletal disorders; History of chronic diseases such as cancer, liver and kidney disease, neurological disorders, diabetes; History of receiving immunoglobulins or other blood products 90 days before the vaccine injection; Pregnancy; Lactation.

Age

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

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider

Sample size

Target sample size: **200**

Randomization (investigator's opinion)

Randomized

Randomization description

Block Randomization method is used to randomized the patients. For randomization, we visited the www.sealedenvelope.com, then randomization tab and make a list option were selected, the number of intervention groups, sample size, block size (which was selected due to the small sample size, 4)were entered the intended locations, then a random list containing the pattern of patient allocation was obtained in two intervention.

Blinding (investigator's opinion)

Double blinded

Blinding description

The study will be done as a double blind RCT. The Vaxigrip vaccine, in a very similar appearance to the Flugaurd vaccine, will be given to the main researcher by the Flugaurd's manufacturer , and the drug and control are distinguished only by the code that only the main researcher is aware of. Prescribers and volunteers will be unaware of the drug / product control. The results will be recorded in the checklist based on the code registered on the drug and the analysis will be done based on the codes. At the end of the study, the meaning of each code will be determined.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Baqiyatallah Medical Sciences University

Street address

Baqiyatallah University of Medical Science, south Sheikh-Bahaei St., Mollasadra St., Vanak Sq., Tehran, Iran

City

Tehran

Province

Tehran

Postal code

۱۴۳۵۹۱۵۳۷۱

Approval date

2020-05-16, 1399/02/27

Ethics committee reference number

IR.BMSU.REC.1399.175

Health conditions studied

1

Description of health condition studied

Seasonal Influenza

ICD-10 code

J09

ICD-10 code description

Influenza due to certain identified influenza viruses

Primary outcomes

1

Description

The ratio of antibody titer against hemagglutinin protein type A H1N1 with GMT scale compared to the control group at day 28 days;

Timepoint

At the baseline, then on day 28.

Method of measurement

Blood sampling.

2

Description

The ratio of antibody titer against hemagglutinin protein type A H3N2 with GMT scale compared to the control group at day 28 days;

Timepoint

At the baseline, then on day 28.

Method of measurement

Blood sampling.

3

Description

The ratio of antibody titer against hemagglutinin protein type B Yamagata with GMT scale compared to the control group at day 28 days;

Timepoint

At the baseline, then on day 28.

Method of measurement

Blood sampling.

4

Description

The ratio of antibody titer against hemagglutinin protein type B Victoria with GMT scale compared to the control group at day 28 days;

Timepoint

At the baseline, then on day 28.

Method of measurement

Blood sampling.

5

Description

Seroconversion rate difference against hemagglutinin protein type A H1N1 after 28 days compared to the control group;

Timepoint

At the baseline, then on day 28.

Method of measurement

Blood sampling.

6

Description

Seroconversion rate difference against hemagglutinin protein type A H3N2 after 28 days compared to the control group;

Timepoint

At the baseline, then on day 28.

Method of measurement

Blood sampling.

7

Description

Seroconversion rate difference against hemagglutinin protein type B Yamagata after 28 days compared to the control group;

Timepoint

At the baseline, then on day 28.

Method of measurement

Blood sampling.

8

Description

Seroconversion rate difference against hemagglutinin protein type B Victoria after 28 days compared to the control group;

Timepoint

At the baseline, then on day 28.

Method of measurement

Blood sampling.

Secondary outcomes

1

Description

The rate of occurrence of any local or systemic solicited complication;

Timepoint

Daily (from day 0 till the end of day 6)

Method of measurement

Monitoring by phone.

2

Description

The rate of occurrence of any unsolicited complication;

Timepoint

Daily

Method of measurement

Monitoring by phone

3

Description

The occurrence rate of any serious side adverse effect;

Timepoint

Daily

Method of measurement

Monitoring by phone

4

Description
Seroconversion rate against A H1N1 hemagglutinin protein after 28 days;
Timepoint
Baseline, then at day 28.
Method of measurement
Blood sample.

5

Description
Seroconversion rate against A H3N2 hemagglutinin protein after 28 days;
Timepoint
Baseline, then at day 28.
Method of measurement
Blood sample.

6

Description
Seroconversion rate against B Yamagata hemagglutinin protein after 28 days;
Timepoint
Baseline, then at day 28.
Method of measurement
Blood sample.

7

Description
Seroconversion rate against B Victoria hemagglutinin protein after 28 days;
Timepoint
Baseline, then at day 28.
Method of measurement
Blood sample.

8

Description
Seroprotection rate against A H1N1 hemagglutinin protein after 28 days;
Timepoint
Baseline, then at day 28.
Method of measurement
Blood sample.

9

Description
Seroprotection rate against A H3N2 hemagglutinin protein after 28 days;
Timepoint
Baseline, then at day 28.
Method of measurement
Blood sample.

10

Description
Seroprotection rate against B Yamagata hemagglutinin protein after 28 days;
Timepoint
Baseline, then at day 28.
Method of measurement
Blood sample.

11

Description
Seroprotection rate against B Victoria hemagglutinin protein after 28 days;
Timepoint
Baseline, then at day 28.
Method of measurement
Blood sample.

12

Description
changes in biochemistry and hematologic parameters (Sr Cr، BUN، ALT، AST، Bilirubin total & direct، CBC diff، Platelet،CD4, CD8, IgM, IgG INR، PTT، PT)
Timepoint
Baseline, then at day 28.
Method of measurement
Laboratory analysis of blood sample.

13

Description
Changes in Tumor Necrotizing Factor(TNF)-alfa serum level;
Timepoint
Baseline, then at day 28.
Method of measurement
Elisa Kit.

14

Description
Changes in Interleukin-1 serum level;
Timepoint
Baseline, then at day 28.
Method of measurement
Elisa Kit.

15

Description
Changes in Interleukin-6 serum level;
Timepoint
Baseline, then at day 28.
Method of measurement
Elisa Kit.

Intervention groups

1

Description
Intervention group: Pre-filled syringe of Flugaurd (the seasonal influenza vaccine, manufactured by Newad Farmad Salamat), 45 mg HA/serotype/dose,

intramuscular injection (non-dominant hand deltoid muscle) in the amount of 0.5 ml in the first visit

Category

Prevention

2

Description

Control group: Pre-filled syringe of Vaxigrip (the seasonal influenza vaccine, manufactured by Sanofi), 45 mg HA / serotype / dose, intramuscular injection (non-dominant hand deltoid muscle) in the amount of 0.5 ml in the first visit

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Baqiyatallah hospital

Full name of responsible person

Mostafa Ghanei

Street address

Baqiyatallah hospital, Mollasadra St., Vanak Sq., Tehran, Iran.

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Tehran

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Email

mghaneister@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Niwad-Pharmed-Salamat company

Full name of responsible person

Amirhossein Abdolghafari

Street address

No. 56, Habibollah St., Azadi St.

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Tehran

Province

Tehran

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Phone

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Email

amirhosein172@hotmail.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Niwad-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

Bagheiat-allah University of Medical Sciences

Full name of responsible person

Nematollah Jonaidi

Position

Professor

Latest degree

Specialist

Other areas of specialty/work

Infectious diseases

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Person responsible for scientific inquiries

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Position

Professor

Latest degree

Specialist

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Critical Care Pharmacotherapy

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Latest degree
Specialist

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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
Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available

Analytic Code
Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available