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FluGuard® Vaccine Information

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CDC:

"As long as flu viruses are circulating, vaccination should continue, even in January or later."

FluGuard® Description

FluGuard®

- Recombinant Quadrivalent Influenza Vaccine
- Sf9 + Baculuvirus System used in NIVAD Co.
- Pre-clinical study (acute and sub-chronic toxicity test) on Rats
- 0.5 mL Pre-filled syringes for Intramuscular Injection
- For persons **18 years and older**

Clinical Trials

Clinical Trial Phase III

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

Clinical Trial Phase III Extension

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.

Clinical Trial Phase III

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

Eligibility Criteria

Inclusion criteria:

- Age between 18-49 Have general health Sign informed consent
- Be able to accompany with the visit programs and study process

Inclusion criteria:

- History of previous vaccinations against influenza strains used in injectable vaccines during the previous 6 months
- 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

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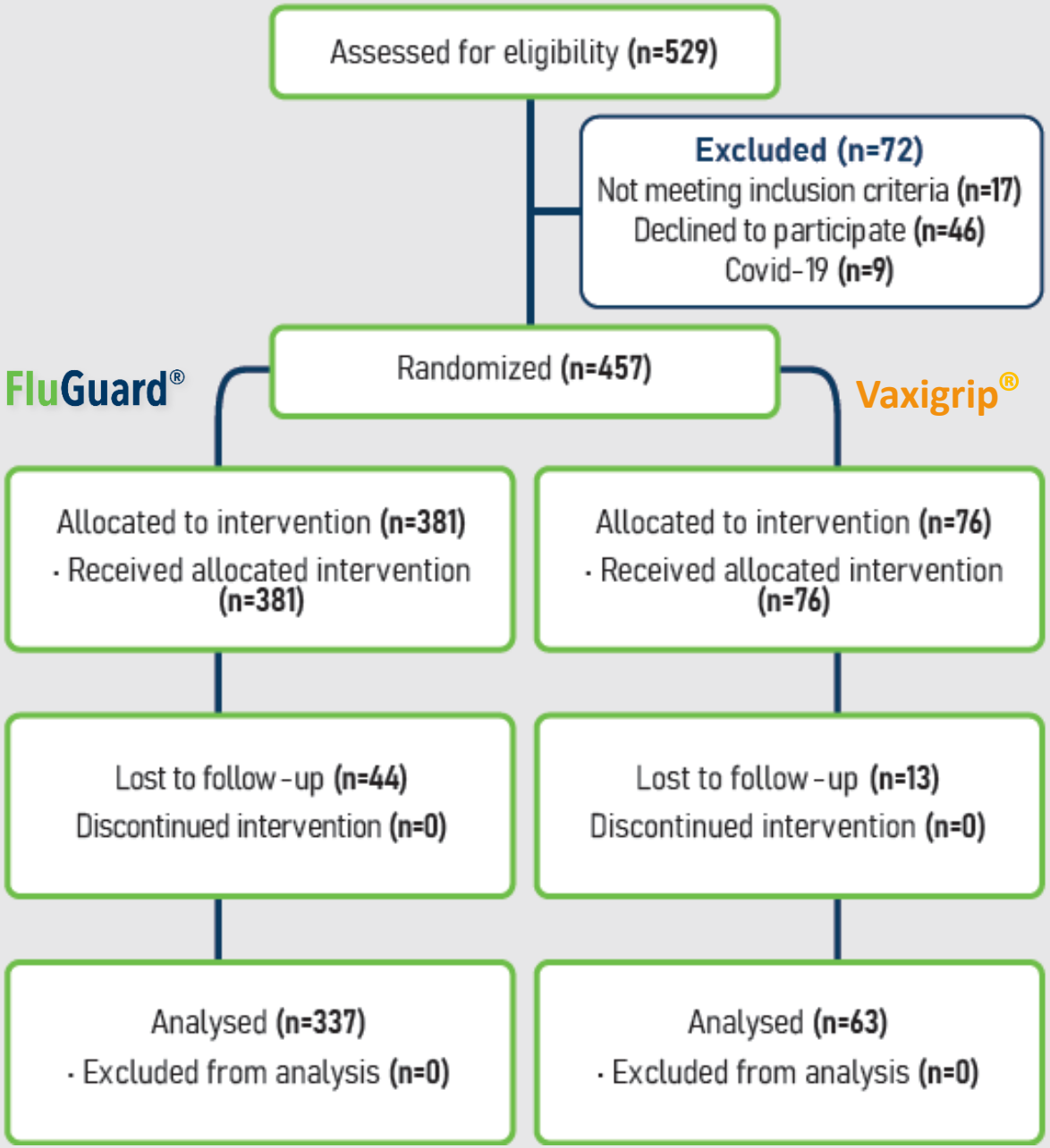
CONSORT Flow Diagram



FluGuard®

نیوا فارمد سلامت (سهامی خاص)

Immunogenicity Results

- $GMT_{\text{U.S. licensed vaccine}}/GMT_{\text{new vaccine}}$

	GMT Ratio (Vaxigrip®/FluGuard®)		
	U CI	Average	L CI
A H1N1	0.840	0.735	0.624
A H3N2	1.134	0.999	0.881
B Yam	1.260	1.134	1.020
B Vic	1.496	1.319	1.163

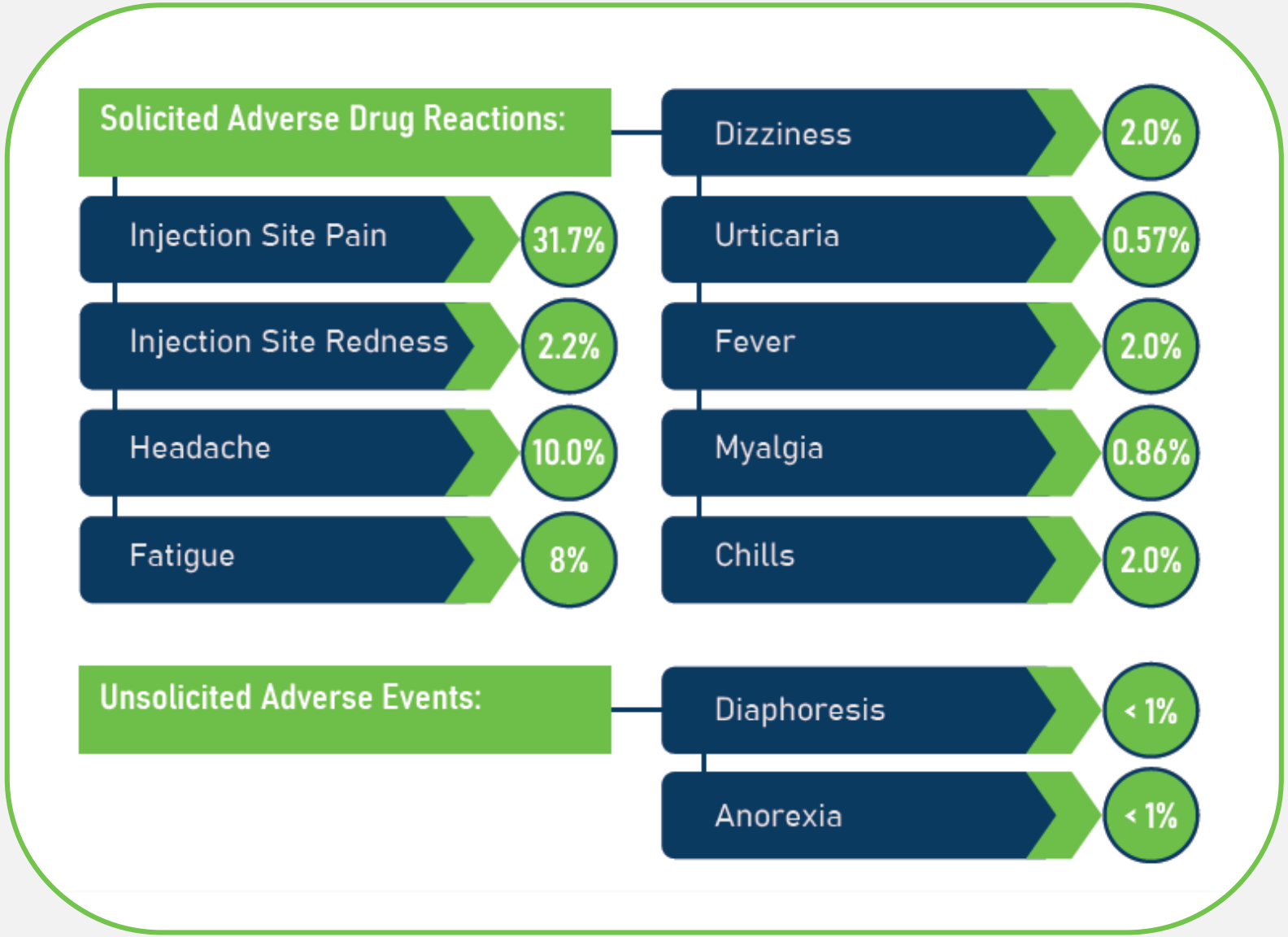
- The upper bound of two-sided 95% CI on the ratio of the GMTs did not exceed 1.5

- $\text{Seroconversion}_{\text{U.S. licensed vaccine}} - \text{Seroconversion}_{\text{new vaccine}}$

	Seroconversion (Vaxigrip®-FluGuard®) (%)		
	U CI	Average	L CI
A H1N1	-4	-11	-18
A H3N2	-1	-8	-15
B Yam	6	0	-7
B Vic	7	0	-6

- The upper bound of two-sided 95% CI on the difference between the seroconversion rates of all serotypes did not exceed 10% points.

FluGuard Safety Results



FluGuard Trial Conclusion

According to the results of this study, it was concluded that FluGuard® is non-inferior to Vaxigrip®in case of immunogenicity and safety

Clinical Trial Phase III Extension

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.

Eligibility Criteria

Inclusion Criteria

- Age ≥ 18 years old
- Healthy and stable medical conditions (3 months prior)
- Properly informed about the study and having signed the informed consent form

Exclusion Criteria

- Subjects with active infection with signs of SARS-COV-2
- Subjects with temperature ≥38◦C at screening or 72hrs prior
- History of Guillain-Barre syndrome
- History of severe allergic reaction to vaccines
- Subjects who have previously vaccinated against SARS-CoV-2 (14 days prior)
- Subjects intend to receive vaccine up to 14 days after the Fluguard® vaccine according to the national immunization
- Pregnancy & Lactation
- Subjects who intend to participate in other clinical trials in 30 days

Screening

Install Web Application

Inclusion and Exclusion Criteria Assessment

Code Assignment

Setting Time for Injection

Study Site Visit

Informed Consent Form Signature

Medical History, Concomitant Medication, Pregnancy Rapid Test, Fever Check

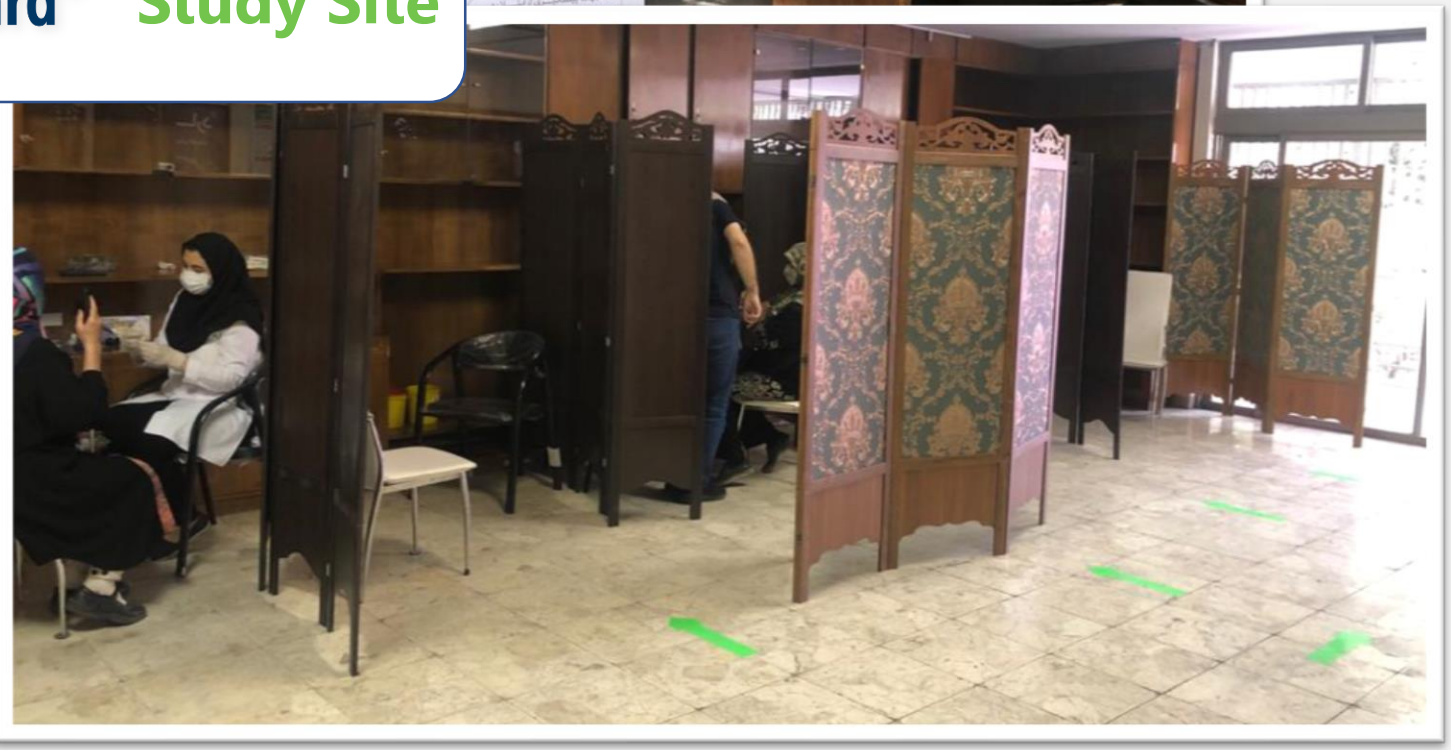
FluGuard® Injection and Monitored for 30 minutes

Follow-up Visits

0 | 0.5 - 24 hr | Day 4 | Day 7 | Day 14 | Day 28 | Day 42

1000 Volunteers

FluGuard® Study Site



FluGuard Solicited Adverse Drug Reactions

Application Site Disorders: Local Pain (43.8%), Redness (6.1%), Swelling (5.4%), Pruritus (3.0%)

Body as a whole-general Disorders: Fatigue (5.6%), Headache (6.34%), Chills (2.4%), Fever (2.2%), Malaise (7.4%)

Musculoskeletal System Disorders: Muscle Pain (3.0%), Back Pain (0.3%), Arthralgia (0.6%)

Gastro-intestinal System Disorders: Nausea (1.3%), Diarrhea (0.4%), Abdominal Pain (0.2%), Vomiting (0.6%), Xerostomia (0.1%)

Respiratory System Disorder: Dyspnea (0.3%), Sneezing Excessive (0.2%), Cough (0.8%), Rhinorrhea (2.3%), Nasal Congestion (0.1%), Sputum Increased (0.1%), Sore Throat (1.2%)

Central and Peripheral Nervous System Disorders: Paresthesia (0.6%), Dizziness (1.8%)

Autonomic Nervous System Disorders: Flushing (1.4%)

Psychiatric Disorders: Somnolence (1.5%)

Skin and Appendages Disorders: Urticaria (0.5%), Rash (0.1%)

Conclusion:

This study provided additional evidence supporting the safety of FluGuard® in adults aged ≥18 years.

THANK YOU
FOR YOUR ATTENTION

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