



Short Communication

Seasonal Influenza Vaccination Randomly Control Trials in Vietnam

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Introduction

RCTs for SI Vaccination among 128 hospitalized patients included Adults ≥ 50 years with COPDs with diabetes, HIV, cardiovascular diseases, renal, hepatic, hematologic metabolic disorders, BMI ≥ 40 ; Children aged 6-59 months and adolescents to 18 years at Bach Mai Hospital, Vietnam since 2019. The clinical study showed that 118 GP examination and X-ray tests, however 128 patients acquired full blood tests and urine tests. In total 112 patients, 98 children obtained Vaxigrip 0.25 ml, 102 adults received Vaxigrip 0.5 ml.

Specific Aims and Hypotheses

IFPMA & Jan Hendriks from WHO Geneva - Apaci Workshop 2013:

- 10 (28%) participating countries among 36 Western Pacific countries reported that SI Vaccination was not available.
- Low-/middle-income countries as Vietnam would be supported to develop influenza vaccine manufacturing capabilities and capacity for pandemic readiness.
- According to Vietnam's regulatory strengthening roadmap from WHO, workshop on trend of SIV would be conducted in December 2014.

John Tam's Presentation Discussion with APACI-Asia-Pacific Influenza Workshop on October, 2013:

- Limitation of Studies on high-quality RCTs
- Lack of RCT-based analyses, Vietnam

Gaps in evidence: pandemic (H1N1) 2009 influenza Vaccination Economic Evaluation, co- morbidities (e.g. HIV)

Background

The MIMS treatment guidelines, 2018 noted that the clinical spectrum of influenza ranges from asymptomatic infection to

primary viral pneumonia that might progress to death. Pneumonia was the most common complication of influenza virus and other bacteria complications as tracheobronchitis, hemophagocytic syndrome, multi-organ failure, renal failure, acute sinusitis.

Innovation

Research Strategy: RCTs for 128 Patients

Study design

- SIV RCTs for 128 Patients included Adults ≥ 50 years
- Adults ≥ 50 years with COPDs with diabetes, HIV, cardiovascular diseases,
- Renal, hepatic, hematologic metabolic disorders, BMI ≥ 40 .
- Children aged 6-59 months and adolescents to 18 years
- Hospitalized patients

Study settings and populations

- Typical signs and symptoms of seasonal influenza, which were different from avian influenza (H5N1)
- ILI is an acute respiratory infection with temperature of ≥ 37.8 degree, cough, onset
- Within the last 10 days
- Abrupt onset of fever
- Severe myalgia
- Severe dry cough
- Loss of appetite
- Headache
- Malaise
- Sore Throat

- Rhinitis
- The study would exclude residents of institutions for physically and mentally disabled; pregnant women, caregivers living with/without the high-risk individuals.

Interventions

- Full Blood test and Urine Test were taken to 128 patients; but 118 patients acquired X-ray test and GP examination.
- There were 102 adults patients that received Vaxigrip 0,5 ml; only 98 children patients obtained Vaxigrip 0,25ml

Sample Size

- Two-sided significance level (1-alpha): 95
- Power (1-beta, % chance of detecting): 80
- Ratio of sample size, Unexposed/Exposed: 1
- Percent of Unexposed with Outcome: 5
- Percent of Exposed with Outcome: 25
- Odds Ratio: 6.3
- Risk/Prevalence Ratio: 5
- Risk/Prevalence difference: 20
- Sample Size-Exposed: 51 49 59

- Sample Size- Nonexposed: 51 49 59

- Total sample size: 102 98 118

Data Analysis

- Typically administer annual vaccinations to high-risk individuals and their contacts from September to November; rainy seasons. Rapid Lab-confirmed influenza would be done in 10-20 minutes to detect influenza A and B viruses in the BM hospital; according to WHO recommended that laboratories with no capacity for diagnosis of influenza A viruses sent representative specimens from suspect cases of influenza to hospital lab.
- If the results were negative, viral culture needed to be instated within 48 hours of symptoms. In 2-10 days or RT-PCR may be indicated for persons with animals 'exposure with possible Influenza illness types and subtypes (H5N1 virus infection) in <5 hours. Symptoms within 2-5 days onset (influenza A or B illness) were differentiate with avian influenza (H5N1)
- The recommended preventive drugs of complications were prescribed Oseltamivir or Zanamivir
- Uncomplicated influenza illness typically resolved after 3-7 days for most patients.