Influenza H1N1 Immunogenicity study

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Primary Objectives: • To determine the basic immunity against influenza H1N1 (2009) in the population.• To determine the humoral and cellular immunity after a single vaccination with Influenza A virus (H1N1) 2009 Monovalent MF59- Adjuvanted Vaccine...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Viral infectious disorders
Study type	Observational invasive

Summary

ID

NL-OMON32857

Source
ToetsingOnline

Brief title
Tilburg Study

Condition

- Viral infectious disorders

Synonym
flu, Influenza

Research involving
Human

Sponsors and support

Primary sponsor: Sint Elisabeth Ziekenhuis
Source(s) of monetary or material Support: eigen ziekenhuis;Sint Elisabeth Ziekenhuis

Intervention

Keyword: Immunogenicity, influenza virus, vaccination

Outcome measures

Primary outcome

The study parameters for humoral immune response are

hemagglutination-inhibition antibodies titers. Sera will be analyzed by a

hemagglutination-inhibition (HAI) test, according to standard procedures.

The induction of cellular immunity will be measured according to Bodewes et al.

(11) and will take place at the Erasmus Medical Center, Rotterdam.

Secondary outcome

none

Study description

Background summary

The emergence of a new pandemic influenza virus will give many deaths and serious complications in vulnerable populations. The World Health Organisation (WHO) declared on June 11, 2009 the first influenza pandemic in 41 years (1). Up till the 23th of October a total of 205 patients are hospitalized and 6 patients died of the new influenza H1N1 in The Netherlands. Sixty-one % of the hospitalized patients suffered from an underlying medical condition (2). Influenza virus causes a specific clinical picture characterized by sudden onset of fever, headache, malaise, myalgias, cough and other respiratory complaints. Adults >= 65 years, pregnant woman, people with underlying medical conditions and children <= 1 year are at greater risk of developing complications (3, 4). Preliminary reports show also a greater risk of complications in the age group of 5 till 14 years (2). Secondary bacterial pneumonia, exacerbations of underlying pulmonary and cardiac disease are examples of possible complications of influenza (3). People born before 1950 seem to have some pre-existing immunity against the influenza virus H1N1 (2009) (5).
Vaccination is the most important tool for reducing morbidity, mortality, virus transmission and preventing infection. The vaccine currently used in the Netherlands is Focetria ® (Novartis). This Influenza A(H1N1) 2009 monovalent vaccine is an inactivated influenza virus vaccine, containing the influenza virus A/California/7/2009 (H1N1)v like strain (X-179A) and the MF59 adjuvant. MF59, an oil-in-water emulsion, is an adjuvant developed to improve the

performance of vaccines in general (6) and has been shown to improve immune response to seasonal influenza vaccines, even in children (7, 8).
The aim of this confirmatory (phase IV)-study is to determine the humoral and cellular immunity before and after vaccination with the Influenza A virus (H1N1) 2009 Monovalent MF59-Adjuvanted Vaccine (Focetria ®, Novartis, a vaccine registered by EMEA). In addition, the study will reveal data on the need of giving a second dose of the vaccine.

Study objective

Primary Objectives:
• To determine the basic immunity against influenza H1N1 (2009) in the population.
• To determine the humoral and cellular immunity after a single vaccination with Influenza A virus (H1N1) 2009 Monovalent MF59- Adjuvanted Vaccine.
• To determine the humoral and cellular immunity after the second vaccination with Influenza A virus (H1N1) 2009 Monovalent MF59-Adjuvanted Vaccine.
• To study the impact of earlier seasonal vaccination on the immune response against the influenza virus H1N1 (2009).

Secondary Objective(s):
• To determine the requirement of a second vaccination with Influenza A virus (H1N1) 2009 Monovalent MF59-Adjuvanted Vaccine.

Study design

Multi-center study from November 2009 through December 2009. 200 subjects will be enrolled in this study.
The study will take place in the St. Elisabeth Hospital (EZ) and the TweeSteden Hospital (TS).

- Cohort study
± 100 subjects will be asked to give 1 blood sample (1 blood tube) each time before
vaccination the with influenza virus H1N1(2009) first dose, second dose and seasonal
vaccination to determine their immunity against influenza H1N1 (2009).
- Subset: Case control study
Influence of seasonal vaccination on the gained immunity for influenza virus H1N1.
100 subjects will be asked to give a blood sample (2 blood tubes) each time before
vaccination with H1N1(2009) first dose, second dose and seasonal vaccination to
determine the influence of seasonal vaccination on the immunity for influenza H1N1(2009). The 100 subjects will be divided into two groups.

Group 1: 50 subjects who received annually the seasonal vaccine and Group 2: 50
subject who never received the seasonal vaccine.

Study burden and risks

There are no personal benefits or risks entering this study. There is only a small burden in having venapunctions and only once a very short questionnaire has to be filled in (duration approximately 2 minutes).

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

All the subjects are between 18 and 65 years of age

Exclusion criteria

none

Study design

Design

Study phase:	4
Study type:	Observational invasive
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	11-11-2009
Enrollment:	200
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Focetria

Ethics review

Approved WMO

Date:	11-11-2009
Application type:	First submission
Review commission:	METC Brabant (Tilburg)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
EudraCT	EUCTR2009-017138-36-NL
CCMO	NL30493.008.09