New influenza A (H1N1) disease incidence and immunogenicity of the pandemic influenza A(H1N1) vaccine in healthy adults

Published: 08-10-2009
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Primary: Evaluate new influenza A (H1N1) disease (pandemic influenza) incidence of vaccinated compared to unvaccinated individuals. Secondary: * Obtain data on immunogenicity of pandemic influenza vaccination:- Evaluation of the humoral immune...

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

Summary

ID

NL-OMON35537

Source
ToetsingOnline

Brief title
Incidence of new H1N1 influenza and its vaccine immunogenicity

Condition

- Viral infectious disorders

Synonym
flu, influenza

Research involving
Human

Sponsors and support

Primary sponsor: Registratie en Medische Unit

Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: immunogenicity, Incidence, Influenza Vaccines, Swine-Origin Influenza A H1N1 Virus

Outcome measures

Primary outcome

Primary: pandemic influenza virus identification after reporting of

influenza-like symptoms by the participants.

Secondary outcome

Secondary:

- The humoral immune response against pandemic influenza vaccine at each of the

specified time points.

- The cellular immune response against pandemic influenza vaccine at each of

the specified time points.

- The humoral and cellular, cross-specific and specific immune responses

against the pandemic influenza virus in the pre-vaccination samples and in the

unvaccinated group.

Added with reference to the extension:

* the humoral and cellular immune responses against influenza A (H3N2) vaccine.

Study description

Background summary

Recently, pandemic H1N1 vaccines have been obtained by the government for the

entire Dutch population. However, at this point only the risk groups that also recieve seasonal vaccination and health care workers, will recieve the vaccine. We will investigate the incidence of pandemic influenza in vaccinated versus unvaccinated individuals and the immunogenicity of the vaccine. This has important implications for future influenza vaccination campaigns and for the development of vaccines.

The WHO has just announced that the pandemic A/California/7/2009-like H1N1 vaccine strain will be included in the Northern Hemisphere 2010-2011 seasonal vaccine, to replace the influenza A (H1N1) strain that was used before the pandemic. This is the same strain that was used in the adjuvanted pandemic influenza vaccine Focetria (2009).
The study will be extended for the duration of the next influenza season to investigate long-term effects of the pandemic vaccine, either or not followed by a seasonal vaccination (see next paragraph). New Informed Consent will be obtained from participants for the extension.
The boosting capacity of the unadjuvanted seasonal vaccine, one year after vaccination with the adjuvanted pandemic vaccine, will be evaluated. In addition, long term immunogenicity will be measured one year after vaccination with the pandemic vaccine. This will be done in pre-vaccination samples of the group who will receive the seasonal 2010-2011 vaccine, but also in the individuals who received the pandemic vaccine but do not wish to receive the seasonal vaccine.
We will continue to measure influenza A (H1N1) incidence.

Study objective

Primary: Evaluate new influenza A (H1N1) disease (pandemic influenza) incidence of vaccinated compared to unvaccinated individuals.
Secondary:
* Obtain data on immunogenicity of pandemic influenza vaccination:
- Evaluation of the humoral immune response to the vaccine and correlate this to protection against the virus.
- Evaluation of the cellular response to the vaccines and correlate this to protection against the virus.
- Evaluation of the response to the second dose of the pandemic influenza vaccine.

* Evaluation of cross-specific immune responses to pandemic H1N1 virus in the pre-vaccination samples.
* Evaluation of specific immune responses against pandemic H1N1 virus in infected, unvaccinated controls.

Added with reference to the extension:
* Obtain data on immunogenicity of adjuvanted pandemic influenza A (H1N1) vaccination more than one year after vaccination
* Evaluation of the boosting capacity of unadjuvanted seasonal influenza A

(H1N1) vaccination
* Evaluation of humoral and cellular immune responses to influenza A (H3N2) vaccin

Study design

Open, controlled, single-blinded, clinical trial with an authorized vaccine and with invasive measurements.

Intervention

Vaccination with pandemic influenza vaccine Focetria from Novartis.

Added with reference to the extension:
Voluntary vaccination with seasonal influenza vaccin 2010-2011.

Study burden and risks

The burden associated with participation is considered low. Participants are vaccinated twice (not the control group). In the vaccinated group blood samples are drawn (3 times 7 tubes, 60 ml, and 2 times 1 tube, 10 ml). In the unvaccinated group 7 tubes, 60 ml blood samples are drawn twice.
Some attention is required for reporting of influenza-like illness. A nose swab is taken from patients that report with influenza like illness.

The potential risks are considered minor. Subjects may experience adverse reactions to the vaccine. Such adverse reactions are usually mild and of short duration. The potential risks of venapuncture are mild pain and haematoma, and are considered negligible. The taking of the nose swab in case of influenza-like illness can be painful.
As a benefit, individual subjects in the vaccination arm of the trial are able to obtain vaccination against pandemic influenza and may benefit from the protection conferred by the vaccinations. There are no benefits for the individual subjects in the unvaccinated group. The findings will have important implications for future pandemic and seasonal influenza vaccination campaigns. The results are possibly of benefit on a population level in the future.

Added with reference to the extension:
From participants who obtain the voluntary seasonal vaccine 2010-2011, three additional blood samples are drawn (2 times 7 tubes, 60 ml, and 1 times 1 tube, 10 ml). From participants who do not obtain the voluntary seasonal vaccine 2010-2011, two additional blood samples are drawn (2 times 7 tubes, 60 ml).

Contacts

Public
Selecteer

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Scientific
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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

* good self-reported health according to the investigator
* willingness and ability to adhere to the study regimen
* having a signed informed consent form
* age 18 * 52 years

Exclusion criteria

The exclusion criteria with regard to contra-indications for receiving the pandemic influenza vaccine are:
* allergy to any of the components of the vaccine or trace residues of eggs, chicken proteins, kanamycin and neomycin sulphate, formaldehyde and cetyltrimethylammonium bromide

(CTAB).
The exclusion criteria with regard to blood collection and the immunological analysis are:
* immune deficiencies
* haematological disorders
* bleeding disorders
* usage of anticoagulants, corticosteroids, NSAIDs and/or statins
* diabetes mellitus
* having had an infectious disease with fever within the last two weeks
* previously diagnosed with pandemic H1N1 influenza

Study design

Design

Study phase:	4
Study type:	Interventional
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Other

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	26-10-2009
Enrollment:	375
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Focetria
Product type:	Medicine
Brand name:	Influvac subunit vaccine
Product type:	Medicine
Brand name:	Vaxigrip

Ethics review

Approved WMO Date:	08-10-2009
Application type:	First submission
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)
Approved WMO Date:	09-10-2009
Application type:	First submission
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)
Approved WMO Date:	29-10-2009
Application type:	Amendment
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)
Approved WMO Date:	16-11-2009
Application type:	Amendment
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)
Approved WMO Date:	26-05-2010
Application type:	Amendment
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)
Approved WMO Date:	01-07-2010
Application type:	Amendment
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)

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	EUCTR2009-014770-17-NL
CCMO	NL29241.000.09