Incidence of pandemic influenza and the immunogenicity of the pandemic vaccin.

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON29324

Source
Nationaal Trial Register

Brief title
N/A

Health condition

Influenza, pandemic (H1N1) 2009, flu
Influenza, pandemische griep, griep

Sponsors and support

Primary sponsor: Netherlands Vaccin Institute
Source(s) of monetary or material Support: VWS

Intervention

Outcome measures

Primary outcome

Evaluation of pandemic influenza incidence of vaccinated subjects compared to unvaccinated subjects.

Secondary outcome

1. Obtain data on immunogenicity of pandemic influenza vaccination;

a. Evaluation of the humoral immune response to the vaccine and correlate this to protection against the virus;

b. Evaluation of the cellular response to the vaccines and correlate this to protection against the virus;

c. Evaluation of the response to the second dose of the pandemic influenza vaccine.

2. Evaluation of cross-specific immune responses to pandemic H1N1 virus in the pre-vaccination samples;

3. Evaluation of specific immune responses against pandemic H1N1 virus in infected, unvaccinated controls;

4. Obtain data on immunogenicity of adjuvanted pandemic influenza A (H1N1) vaccination more than one year after vaccination;

5. Evaluation of the boosting capacity of unadjuvanted seasonal influenza A (H1N1) vaccination;

6. Evaluation of humoral and cellular immune responses against influenza A (H3N2) vaccine.

Study description

Background summary

We will investigate the incidence of pandemic influenza in healthy adults between 18 and 52 years of age that have either received the pandemic influenza vaccine or not and analyze whether humoral and cellular immune responses correlate with protection against influenza. The findings will have important implications for future pandemic and seasonal influenza vaccination campaigns.

Study objective

Evaluation of pandemic influenza incidence of vaccinated subjects compared to unvaccinated subjects in correlation with immunogenicity of the vaccine.

Study design

Timepoint 1: Presample blood and first vaccination;

Timepoint 2: Bloodsample 10-14 days after vaccination;

Timepoint 3: Bloodsample 3 weeks after first vaccination and second vaccination;

Timepoint 4: Blood sampling 3 weeks after second vaccination;

Timepoint 5: Nose swab, applicable if influenza-like illness is reported;

Timepoint 6: Bloodsampling at end of pandemic;

Timepoint 7: Bloodsample 1 year after vaccination;

Timepoint 8: Bloodsample 3 weeks after timepoint 7 (if additional influenza vaccination is administered);

Timepoint 9: Bloodsample at end of influenza season 2010/2011.

Intervention

Healthy adults will be vaccinated 2 times with a 3 week interval with the pandemic influenza vaccin Focetria (Novartis). At the described timepoints blood sampling will take place for immunological analysis. In the control group, individuals will not be vaccinated and bloodsampling will take place at timepoint 1 and 6.

In both groups, a nose swab will be taken when an individual reports influenza-like symptoms to confirm the presence of pandemic H1N1 virus. Primary endpoint of the study is the difference in the percentage of individuals infected with the pandemic influenza virus in both arms of the study.

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Eligibility criteria

Inclusion criteria

1. Good self-reported health according to the investigator;

2. Willingness and ability to adhere to the study regimen;

3. Having a signed informed consent (IC) form;

4. Age 18 – 65 years.

Exclusion criteria

The exclusion criteria with regard to contra-indications for receiving the pandemic influenza vaccine are:

1. 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:

1. Immune deficiencies;

2. Haematological disorders;

3. Bleeding disorders;

4. Usage of anticoagulants, corticosteroids, NSAIDs and/or statins;

5. Diabetes mellitus;

6. Having had an infectious disease with fever within the last two weeks;

7. Previously diagnosed with pandemic H1N1 influenza.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Non-randomized controlled trial
Masking:	Single blinded (masking used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	26-10-2009
Enrollment:	375
Type:	Anticipated

Ethics review

Positive opinion

Date:	04-08-2009
Application type:	First submission

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
NTR-new	NL1952
NTR-old	NTR2070
Other	NVI/NL : 255/29241.000.09
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A