Safety and immunogenicity of seasonal and pandemic inactivated whole virion influenza vaccine in healthy adults

Published: 07-02-2011
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The goal of this study is to assess the safety and immunogenicity of the seasonal and pandemic inactivated whole virion influenza vaccines produced with the production process set up by the NVI for technology transfer (proof of principle).

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

Summary

ID

NL-OMON36142

Source
ToetsingOnline

Brief title
Safety and immunogenicity of whole virion influenza vaccines

Condition

- Viral infectious disorders

Synonym
infection, influenza

Research involving
Human

Sponsors and support

Primary sponsor: Stichting Leveronderzoek
Source(s) of monetary or material Support: WHO

Intervention

Keyword: immunogenicity, influenza, safety, vaccine

Outcome measures

Primary outcome

Primary Objective: to assess the safety of seasonal and pandemic inactivated

whole virion influenza vaccine.

Secondary outcome

Secondary Objective(s): to assess immunogenicity of seasonal and pandemic

inactivated whole virion influenza vaccine, and to compare the safety profile

of the whole virion vaccines with a split virion vaccine.

Study description

Background summary

To increase availability of seasonal and especially pandemic influenza vaccines for developing countries it is important that local vaccine production facilities are established. NVI has set up an influenza vaccine production process suitable for technology transfer to manufacturers in lower- and middle income countries. The safety and immunogenicity of a monovalent seasonal and a pandemic inactivated whole virion vaccine will be investigated.

Study objective

The goal of this study is to assess the safety and immunogenicity of the seasonal and pandemic inactivated whole virion influenza vaccines produced with the production process set up by the NVI for technology transfer (proof of principle).

Study design

The study is a phase 1, double-blind, parallel, randomized, placebo-controlled trial (N=120).
The seasonal and pandemic vaccines produced by NVI will be compared with a commercial split virion seasonal vaccine as well as with a placebo. This

results in 3 study groups:
1. Egg-based pilot seasonal influenza vaccine 15 *g HA (n=60)
2. Egg-based pilot pandemic influenza vaccine 15 *g HA (n=30)
3. Commercial seasonal influenza vaccine 3x15 *g HA (split virion) (n=30)

Intervention

Three treatment arms will be included:

1. Seasonal influenza vaccine (one dose) and a placebo dose;
2. Pandemic influenza vaccine (two doses);
3. Commercial seasonal influenza vaccine (one dose) and a placebo dose.

Blood samples are drawn on screening, day 0, day 21 and on day 42. After each dose, subjects are requested to complete a diary for five days to record adverse events.

Study burden and risks

There are no benefits for the individual subjects in this trial. Subjects should make four study visits. During each study visit, subjects are physically examined and blood samples are drawn. The risks of venapuncture are considered negligible. Subjects may experience adverse reactions to the vaccine. Subjects should record adverse events in a diary. Adverse events are expected to be mild and of short duration. The burden of participation in this study is considered low.

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

Age 18 to 49 years
Good health according to the investigator

Exclusion criteria

- having had an infectious disease with fever (including influenza) within the last 14 days
- present evidence of serious disease(s) demanding medical treatment that might interfere with the results of the study such as diseases which interfere with the immune system
- known or suspected allergy to any of the vaccine components: egg components, chicken protein, ovalbumin (by medical history)
- known or suspected immune deficiency
- history of any neurologic disorder, including epilepsy
- females: positive pregnancy test
- positive HIV, HBV or HCV serology
- previous vaccination with an influenza vaccine in the previous three winter seasons
- abnormal pre-treatment laboratory parameters which are clinically relevant according to the investigator

Study design

Design

Study type:	Interventional
Intervention model:	Parallel

Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	14-06-2011
Enrollment:	120
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	niet van toepassing
Product type:	Medicine
Brand name:	Vaxigrip

Ethics review

Approved WMO

Date:	07-02-2011
Application type:	First submission
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)

Approved WMO

Date:	17-05-2011
Application type:	First submission
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
Other	2695
EudraCT	EUCTR2011-000159-17-NL
CCMO	NL35423.000.11