New influenza vaccine based on MVA.

No registrations found.

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

Summary

ID

NL-OMON28138

Source
NTR

Brief title
Fluvec

Health condition

influenza A/H5N1 virus
smallpox (pokken)

Sponsors and support

Primary sponsor: Erasmus Medical Center, Rotterdam, The Netherlands
Source(s) of monetary or material Support: European Research Council (ERC)

Intervention

Outcome measures

Primary outcome

Safety assessment of the MVA-H5-sfMR vaccine in humans in a dose escalation setup and with one or two immunizations. Study subjects will undergo physical examinations will be performed before and on fixed time points during the study phase. Clinical chemistry is performed on the blood samples that are drawn throughout the study and local and systemic reactions are tracked with a daily dairy card during the first week after immunization.

Secondary outcome

Assessment of the immunogenicity of the MVA-H5-sfMR vaccine in humans in a dose escalation setup and with one or two immunizations. The immunogenicity will be determined by measuring influenza-specific antibody titers in the hemagglutination inhibition assay and virus neutralization assay. Furthermore HA-specificity of cytotoxic T cells isolated from the vaccinees will be determined. Besides these responses the immunity against the vector will also be characterized and quantified.

Study description

Background summary

MVA expressing the HA gene from influenza virus A/Vietnam/1194/04 has been studied in depth in mice and a non-human primate model. Initially a two dose immunization regimen was tested in C57Bl6/J mice and induced sterile immunity in these animals against the homologous and heterologous strains.(Kreijtz et al JID 2007) As a follow-up study the two dose regimen was tested in cynomolgus macaques in which it proved to be safe and it induced also sterile immunity against the homologous and heterologous challenge viruses.(Kreijtz et al JID 2009)

In a dose escalation experiment in mice we determined the minimal dose to induce protection against challenge infection and explored the possibility to induce protection with a single immunization. Mice that were immunized once with a relatively high dose (10e8) or twice with a low dose (3log10 lower) were protected against challenge infection with the homologous or heterologous influenza A/H5N1 virus.(Kreijtz et al PLoS One 2009)

Study objective

MVA-based influenza vaccine is safe and immunogenic in young healthy adults.

Study design

1. Before immunization;

2. 1 hour after immunization;

3. 4 weeks after immunization;

4. 4 weeks after second immunization;

5. 20 weeks after second immunization.

Intervention

1 or 2 intramuscular immunizations with an MVA-based influenza vaccine. Two dosages are tested:

1. 10e7 pfu in 0.5ml;

2. 10e8 pfu in 0.5ml.

Contacts

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Eligibility criteria

Inclusion criteria

1. 18-35 years of age;

2. Female volunteers must acquire an acceptable form of contraception during the study period and to have a negative pregnancy test on the days of immunization;

3. Refrain from blood donation during the study period;

4. Written informed consent;

5. Available for the complete study period;

6. Able and willing to comply with all study requirements.

Exclusion criteria

1. Pregnancy or lactation;

2. Acute or chronic illness;

3. Known allergy to eggs, egg products or chicken protein;

4. Previous immunization with a recombinant MVA;

5. Previous immunization with an influenza A/H5N1 vaccine;

6. Pre-existing immunity to influenza A/H5N1 virus;

7. Pre-existing immunity to vaccinia virus.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Active

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	15-10-2012
Enrollment:	80
Type:	Anticipated

Ethics review

Positive opinion

Date:	18-04-2012
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	NL3249
NTR-old	NTR3401
Other	CCMO : 2011-003035-66
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
Kreijtz et al, JID, 2007
Kreijtz et al, JID, 2009
Kreijtz et al, PLoSOne, 2009