New influenza vaccine based on MVA.

Gepubliceerd: 18-04-2012 Laatst bijgewerkt: 18-08-2022

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

Ethische beoordeling	Positief advies
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON28138

Bron
NTR

Verkorte titel
Fluvec

Aandoening

influenza A/H5N1 virus
smallpox (pokken)

Ondersteuning

Primaire sponsor: Erasmus Medical Center, Rotterdam, The Netherlands
Overige ondersteuning: European Research Council (ERC)

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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.

Toelichting onderzoek

Achtergrond van het onderzoek

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)

Doel van het onderzoek

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

Onderzoeksopzet

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.

Onderzoeksproduct en/of interventie

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.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Dubbelblind
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	15-10-2012
Aantal proefpersonen:	80
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	18-04-2012
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL3249
NTR-old	NTR3401
Ander register	CCMO : 2011-003035-66
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten
Kreijtz et al, JID, 2007
Kreijtz et al, JID, 2009
Kreijtz et al, PLoSOne, 2009