Onderzoek naar de bijwerkingen en immuunrespons na een boostervaccinatie tegen polio, toegediend met een naaldloze Jet Injector.

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Changing the route of administration from intramuscular to intradermal may improve the immunogenicity of IPV and allow dose reduction. By using a jet injector instead of a needle and syringe, more antigen can be spared by reducing loss of vaccine...

Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON26044

Bron
Nationaal Trial Register

Aandoening

poliomyelitis, polio, vaccination, vaccinatie, intradermal, intradermaal, jet injector, needle-free, naaldloos

Ondersteuning

Primaire sponsor: Netherlands Vaccine Institute
RIVM, formerly Nederland Vaccine, Institute (NVI)
Overige ondersteuning: Netherlands Vaccine Institute
RIVM, formerly Nederland Vaccine, Institute (NVI), LUMC , Pharmajet

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

1. Safety of injection of IPV with jet injector and of intradermal injection of IPV (local and system reactions);
2. Immunogenicity of intradermal injection of reduced dose IPV versus intramuscular injection of full dose IPV (neutralizing antibody titers in serum).

Toelichting onderzoek

Achtergrond van het onderzoek

Rationale:

For global eradication of poliomyelitis Inactivated Poliovirus Vaccine (IPV) needs to become available for developing countries. This requires a lower price and increased availability of vaccine doses. Antigen sparing by reducing the dose to one-fifth of the standard dose will have a positive effect on both. Changing the route of administration from intramuscular to intradermal may improve the immunogenicity of IPV and thereby allow this degree of dose reduction. By using a jet injector instead of a needle and syringe, more antigen can be spared by reducing loss of vaccine due to dead space volume and removal of air and superfluous fluid. In addition, administration will be both needle-free and needs little training, making it especially suitable for developing countries.

Primary objective is to compare the immunogenicity and safety (local and systemic reactions) of a reduced dose intradermal IPV (NVI) booster vaccination administered with a jet injector to a standard full dose intramuscular IPV (NVI) booster vaccination administered with a needle and syringe.

Doel van het onderzoek

Changing the route of administration from intramuscular to intradermal may improve the immunogenicity of IPV and allow dose reduction. By using a jet injector instead of a needle and syringe, more antigen can be spared by reducing loss of vaccine due to dead space volume and removal of air and superfluous fluid. In addition, administration will be both needle-free and needs little training, making it especially suitable for developing countries.

Onderzoeksopzet

1. Vaccination on day 0;

2. Safety: the participants are asked to keep a diary for 4 day starting on day 0;

3. Blood samples: day 0, 7, 28 and 365;

4. Saliva samples: day 0, 7, 28.

Onderzoeksproduct en/of interventie

Vaccination with inactivated poliomyelitis vaccine (IPV):

1. Reference: 0.5 ml of IPV intramuscular injection with needle and syringe;

2. Group A: 0.5 ml of IPV intramuscular injection with jet injector;

3. Group B: 0.1 ml of IPV intramuscular injection with needle and syringe;

4. Group C: 0.1 ml of IPV intradermal with jet injector.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Age ¡Ý 18 years;

2. Good health according to the investigator;

3. Must have received in total 6 combined DTP-IPV vaccinations according to the NIP as a child (before 11 years of age) and must not have received any polio vaccination since then.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. IPV booster dose after 10 years of age;

2. OPV dose;

3. Known or suspected allergy against any of the vaccine components;

4. History of unusual or severe reactions to any previous vaccination;

5. Known or suspected disease or use of medication that may influence the immune system;

6. History of any neurological disorder including epilepsy or febrile seizures;

7. Pregnancy.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	01-03-2010
Aantal proefpersonen:	120
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies

Datum:	02-02-2010
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	NL2079
NTR-old	NTR2196
Ander register	NL29671.000.09 CCMO / 2009-015175-27 EudraCT number : NVI-250 /
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten
N/A