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

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON26044

Source
Nationaal Trial Register

Health condition

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

Sponsors and support

Primary sponsor: Netherlands Vaccine Institute
RIVM, formerly Nederland Vaccine, Institute (NVI)
Source(s) of monetary or material Support: Netherlands Vaccine Institute
RIVM, formerly Nederland Vaccine, Institute (NVI), LUMC , Pharmajet

Intervention

Outcome measures

Primary outcome

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).

Secondary outcome

Immunogenicity (Neutralizing IgA titers) in saliva and the number of poliospecific IgA-producing B cells in peripheral blood.

Study description

Background summary

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.

Study objective

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.

Study design

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.

Intervention

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.

Contacts

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Eligibility criteria

Inclusion criteria

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.

Exclusion criteria

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.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-03-2010
Enrollment:	120
Type:	Actual

Ethics review

Positive opinion

Date:	02-02-2010

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	NL2079
NTR-old	NTR2196
Other	NL29671.000.09 CCMO / 2009-015175-27 EudraCT number : NVI-250 /
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A