Immunogenicity and safety of intradermal injection of reduced dose Inactivated Poliovirus vaccine (IPV) with a jet injector in healthy adults

Published: 10-11-2009
Last updated: 04-05-2024

The primary objective of this trial 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 (...

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

Summary

ID

NL-OMON32437

Source
ToetsingOnline

Brief title
Intradermal injection of reduced dose IPV with a jet injector in adults

Condition

- Viral infectious disorders

Synonym
infantile paralysis, polio

Research involving
Human

Sponsors and support

Primary sponsor: Nederlands Vaccin Instituut

Source(s) of monetary or material Support: Ministerie van OC&W,Ministerie van VWS

Intervention

Keyword: intradermal administration, IPV, jet injector

Outcome measures

Primary outcome

The level of neutralizing antibodies in serum and the number and intensity of

local and systemic adverse reactions.

Secondary outcome

The number of B-lymphocytes producing IPV-specific IgA in blood and the level

of poliovirus specific IgA antibodies in saliva.

Study description

Background summary

Inactivated poliovirus vaccine (IPV) was first introduced into the market in 1957. It is very effective and safe but due to its high costs it is only used in high-income countries and some middle-income countries. Other countries therefore use an oral poliovirus vaccine based on attenuated polioviruses. Drawback of this vaccine is that in rare cases it can cause poliomyelitis and it can revert to a neurovirulent polio virus. This has caused outbreaks of vaccine-derived polio. For global eradication of poliomyelitis Inactivated Poliovirus Vaccine (IPV) vaccine 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, administration will be both needle-free and need little training, making it especially suitable for developing counties.

Study objective

The primary objective of this trial 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.

Secondary objectives are:
1) to evaluate the immunogenicity and safety (local and systemic reactions) of a full dose intramuscular IPV (NVI) booster vaccination administered with a jet injector compared with a standard full dose intramuscular IPV (NVI) booster vaccination administered with a needle and syringe.
2) to compare the immunogenicity of intradermal and intramuscular vaccination with reduced dose IPV.

Study design

Randomized, controlled clinical trial with 4 arms:

Reference group: Intramuscular injection of 0.5 ml IPV with needle and syringe
Group A: Intramuscular injection of 0.5 ml IPV with jet injector
Group B: Intramuscular injection of 0.1 ml IPV with needle and syringe
Group C: Intradermal injection of 0.1 ml IPV with jet injector

The subjects will receive a single vaccination with IPV. Blood samples will be taken before vaccination and on day 7, 28 and 365 after vaccination. Saliva samples will be taken before vaccination and on day 7 and 28.

Study burden and risks

Four blood samples and three saliva samples will be taken and one vaccination with a well-known vaccine will be given, which requires in total four visits. The participants are asked to fill in a diary during the study. No risks are associated with participation, other than general discomfort that can be experienced after vaccination with IPV and/or after blood sampling.

Contacts

Public
Nederlands Vaccin Instituut

Antonie van Leeuwenhoeklaan 11
3720 AL Bilthoven
NL
Scientific
Nederlands Vaccin Instituut

Antonie van Leeuwenhoeklaan 11
3720 AL Bilthoven
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Subjects have to fulfill all of the following criteria:
• Age >= 18 years
• Good health according to the investigator
• Must have received in total 6 combined DTP-IPV vaccinations according to the National Immunization Programme as a child (before 11 years of age) and must not have received any polio vaccination since then.
• Willingness and ability to adhere to the study regimen
• Having a signed informed consent form

Exclusion criteria

Any of the following criteria will exclude a volunteer from participation, at start of this study:
•IPV booster dose after 10 years of age
•OPV dose
•Known or suspected allergy against any of the vaccine components
•History of unusual or severe reactions to any previous vaccination
•Known or suspected disease or use of medication that may influence the immune system
•Administration of plasma or blood products three months prior to the study
•Any vaccination within one month prior to the study
•History of any neurological disorder including epilepsy or febrile seizures
•Evidence of excessive alcohol use or drug use
•Pregnancy
•Females not willing to use contraceptives during the first 28 days following vaccination, or if

breastfeeding
•Bleeding disorders or the usage of anticoagulants
Delay criteria
•If body temperature >= 38.0°C this will lead to postponement of participation. Screening may continue when the temperature has normalized.

Study design

Design

Study phase:	2
Study type:	Observational invasive
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	16-08-2010
Enrollment:	120
Type:	Actual

Medical products/devices used

Generic name:	Pharmajet;liquid jet injector
Registration:	No

Ethics review

Approved WMO

Date:	10-11-2009
Application type:	Amendment
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den

	Haag)
Approved WMO Date:	10-11-2009
Application type:	First submission
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)
Approved WMO Date:	16-02-2010
Application type:	First submission
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)
Approved WMO Date:	21-10-2010
Application type:	Amendment
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
EudraCT	EUCTR2009-015175-27-NL
CCMO	NL29671.000.09