ISRCTN19673867 https://doi.org/10.1186/ISRCTN19673867

Immune response of fractional doses of Inactivated Poliovirus Vaccine (IPV) administered intradermally in Cuba

Submission date	Recruitment status	[_] Prospectively registered
14/08/2007	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
15/08/2007	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
30/09/2021	Infections and Infestations	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Anna-Lea Kahn

Contact details
Technical Officer
World Health Organization
20 Avenue Appia
Geneva-27
Switzerland
CH-1211
+41 (0)22 791 3135
kahna@who.int

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

RPC171

Study information

Scientific Title
Immune response of fractional doses of Inactivated Poliovirus Vaccine (IPV) administered intradermally in Cuba

Study objectives
1. Does a schedule of three fractional 0.1 ml IPV doses administered intradermally (intervention) provide comparable seroconversion and titre with a three-dose schedule of full 0.5 ml IPV doses (control) administered intramuscularly at 6, 10, and 14 weeks?
2. What is the contribution to seroconversion and titre in each group after the first, second and third dose of study vaccines?
3. What is the influence of maternally-derived antibodies on seroconversion and titre?
4. Does each study arm have comparable adverse events - systemic and local (the intervention group receives fractional doses by needle-free device, while the control group receives full doses by intramuscular injection by needle and syringe)?
5. Do mothers whose study infants were vaccinated by needle-free device (study) and needle and syringe (routine program) express a preference for route for administration after the third vaccination?

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval from:
1. World Health Organization (WHO) Research Ethics Review Committee on the 11th September 2006 (ref: RPC171)
2. Medical ethics committee of the Tropical Medicine Institute (Instituto de Medicina Tropical Pedro Kouri [IPK]) on the 17th August 2006

Study design
Randomised controlled clinical trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied

Poliomyelitis vaccination

Interventions
Patients will be randomised between:
1. A fractional dose of IPV (0.1 ml or 1/5 of a dose) administered intradermally by needle-free device - potency of IPV is 40-8-32-D antigen units
2. A full dose of IPV (0.5 ml) administered intramuscularly by needle and syringe - potency of IPV is 40-8-32-D antigen units

Principal Investigator:
Dr Pedro Mas Lago
c/o Instituto de Medicina Tropical Pedro Kouri (IPK)
Ministerio de Salud Publica
P.O. Box 601
Havana, Mariana 13
Cuba
Tel: +53 (0)7 202 0430
Fax: +53 (0)7 204 6051
Email: pmasl@ipk.sld.cu

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Inactivated Poliovirus Vaccine (IPV)

Primary outcome measure
Seroconversion by neutralisation assay between birth and 18 weeks.

Secondary outcome measures
Seroconversion by neutralisation assay after each dose of study vaccines.

Overall study start date
15/09/2006

Completion date
30/04/2007

Eligibility

Key inclusion criteria
1. Healthy newborns (greater than 2.5 kg, apgar score greater than 9 at five minutes)
2. Living within the catchment area of the participating polyclinics
3. Newborns delivered by caesarian section

Participant type(s)
Patient

Age group
Neonate

Sex
Both

Target number of participants
400

Total final enrolment
320

Key exclusion criteria
1. Newborns requiring hospitalisation (except if in hospital because of maternal admission)
2. Birth weight below 2.5 kg
3. Apgar score less than 9
4. Residence outside the catchment area, or families expecting to move away during the study period
5. A diagnosis or suspicion of immunodeficiency disorder (either in the participant or in a member of the immediate family) will also render the newborn ineligible for the study

Date of first enrolment
15/09/2006

Date of final enrolment
30/04/2007

Locations

Countries of recruitment
Cuba

Switzerland

Study participating centre
Technical Officer
Geneva-27
Switzerland
CH-1211

Sponsor information

Organisation
World Health Organization (WHO) (Switzerland)

Sponsor details
20 Avenue Appia
Geneva-27
Switzerland
CH-1211

Sponsor type
Research organisation

Website
http://www.polioeradication.org/content/fixed/opvcessation/opvcessation.asp

ROR
https://ror.org/01f80g185

Funder(s)

Funder type
Research organisation

Funder Name
World Health Organization (WHO)/Polio Eradication Initiative (POL) (Switzerland)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	31/01/2013	30/09/2021	Yes	No