

Immune response of fractional doses of Inactivated Poliovirus Vaccine (IPV) administered intradermally in the Sultanate of Oman

Submission date 14/08/2007	Recruitment status No longer recruiting	☐ Prospectively registered
Registration date 15/08/2007	Overall study status Completed	☐ Protocol
Last Edited 25/06/2010	Condition category Infections and Infestations	☐ Statistical analysis plan
		☒ Results
		☐ Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
RPC189

Study information

Scientific Title

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 2, 4, and 6 months?
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. Is resistance to excretion of poliovirus type 1 (an indication of mucosal immunity) following a challenge dose with monovalent type 1 Oral Poliovirus Vaccine (mOPV1) similar among the two study groups?

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethics approval received from:

1. World Health Organization (WHO) Research Ethics Review Committee on the 29th January 2007 (ref: RPC189)
2. Ethical Review Committee of the Ministry of Health, Muscat, Oman on the 30th August 2006 (ref: 502)

Primary study design

Interventional

Study design

Randomised controlled clinical trial

Study type(s)

Treatment

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

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Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Inactivated Poliovirus Vaccine (IPV)

Primary outcome(s)

Seroconversion after three doses of IPV (fractional or full doses).

Key secondary outcome(s)

Seroconversion after each dose of vaccine.

Completion date

30/10/2007

Eligibility**Key inclusion criteria**

1. Healthy Omani newborns (greater than 2.5 kg, apgar score greater than 9 at five minutes)
2. Living within the catchment area of the participating study site
3. Newborns delivered by caesarean section

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Neonate

Sex

All

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 at five minutes
4. Non-Omani
5. Residence outside the catchment area, or families expecting to move away during the study period
6. 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

15/02/2007

Date of final enrolment

30/10/2007

Locations

Countries of recruitment

Oman

Switzerland

Study participating centre**Technical Officer**

Geneva-27

Switzerland

CH-1211

Sponsor information

Organisation

World Health Organization (WHO) (Switzerland)

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

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	24/06/2010		Yes	No