ISRCTN17418767 https://doi.org/10.1186/ISRCTN17418767

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 [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 15/08/2007	**Overall study status** Completed	
Last Edited 25/06/2010	**Condition category** Infections and Infestations	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Pradeep Malankar

Contact details
Technical Officer
World Health Organization
20 Avenue Appia
Geneva-27
Switzerland
CH-1211
+41 (0)22 791 1863
malankarp@who.int

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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)

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 Ali Jaffer Mohammed
P.O. Box 393
Muscat 113
Oman
Tel: +968 (0)600808
Fax: +968 (0)696099
Email: alijamoh@omantel.net.om

Intervention Type
Drug

Phase
Not Specified

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

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

Secondary outcome measures
Seroconversion after each dose of vaccine.

Overall study start date
15/02/2007

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

Age group

Neonate

Sex
Both

Target number of participants
400

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)

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	24/06/2010		Yes	No