

# Evaluation of humoral immune response induced by a supplemental dose of inactivated poliovirus vaccine (IPV) administered intradermally or intramuscularly versus a dose of monovalent type 1 oral poliovirus vaccine

<b>Submission date</b> 26/11/2008	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered
<b>Registration date</b> 26/11/2008	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 08/05/2012	<b>Condition category</b> Infections and Infestations	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> 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**  
RPC300

# Study information

## Scientific Title

## Study objectives

Determine if there is a greater than or equal to 4-fold rise in antibody titres measured by neutralisation assay, 28 days after a single dose of intramuscular full-dose IPV GSK or intramuscular full-dose IPV panacea or intradermal fractional-dose IPV or mOPV1 higher potency (Sanofi Pasteur) or mOPV1 lower potency (panacea).

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

Sanchetana IEC pending approval as of 26/11/2008

## Study design

Randomised controlled unblinded trial

## Primary study design

Interventional

## Study type(s)

Treatment

## Health condition(s) or problem(s) studied

Poliomyelitis

## Interventions

1. Intervention group one: one fractional dose of IPV by GSK (0.1 ml or 1/5 of a dose)
2. Control group one: a full dose of IPV (0.5 ml) by GSK
3. Control group two: a full dose of IPV (0.5 ml) by Panacea
4. Control group three: one dose of mOPV type 1 by Panacea (potency  $10^{6.15}$  TCID<sub>50</sub> in 0.1 ml)
5. Control group four: one dose of mOPV type 1 (potency  $10^{6.8}$  TCID<sub>50</sub> in 0.1 ml) by Sanofi Pasteur

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## Intervention Type

Drug

**Phase**

Not Specified

**Drug/device/biological/vaccine name(s)**

Poliovirus vaccine

**Primary outcome(s)**

1. To evaluate whether intradermal administration of one-fifth of the standard IPV dose provides seroconversion rates and titres against all 3 serotypes comparable with the full 0.5 ml IPV dose administered intramuscularly
2. To determine whether IPV induces higher seroconversion rates and antibody titres (significant booster effect) to type 1 poliovirus compared to mOPV 1 in infants 6 - 9 months of age who have been exposed to several OPV doses
3. To characterise the immune response of the trial vaccination as primary (priming) or secondary (boosting), through measurement of antibody titres reached at 7 days and through determination of immunoglobulin A and M by ELISA

**Key secondary outcome(s)**

1. To assess whether one dose of IPV manufactured by Panacea administered intramuscularly elicits the same immune response as one dose of IPV manufactured by GlaxoSmithKline (both with 40-8-32 D antigen potency)
2. To assess whether Sanofi-Pasteur mOPV1, with 4-fold higher vaccine virus dosage compared to Panacea mOPV1, induces higher seroconversion rates and antibody titres to poliovirus type 1 than Panacea mOPV1

**Completion date**

10/02/2009

**Eligibility****Key inclusion criteria**

1. Healthy children in the target group (6 - 9 months at baseline, either sex)
2. Resident in Moradabad district, Uttar Pradesh, India

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Child

**Lower age limit**

6 months

**Upper age limit**

9 months

**Sex**

All

**Key exclusion criteria**

Children with chronic illness

**Date of first enrolment**

10/01/2009

**Date of final enrolment**

10/02/2009

## Locations

**Countries of recruitment**

India

Switzerland

**Study participating centre**

**World Health Organization**

Geneva

Switzerland

CH-1211

## Sponsor information

**Organisation**

Panacea Biotech Limited (India)

**ROR**

<https://ror.org/01ew11x49>

## Funder(s)

**Funder type**

Research organisation

**Funder Name**

World Health Organization (WHO) (Switzerland)

**Alternative Name(s)**

, , Всемирная организация здравоохранения, Organisation mondiale de la Santé, Organización Mundial de la Salud, WHO, , ВОЗ, OMS

### Funding Body Type

Government organisation

### Funding Body Subtype

International organizations

### Location

Switzerland

## Results and Publications

### Individual participant data (IPD) sharing plan

#### IPD sharing plan summary

#### Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>	results	01/02/2012		Yes	No