ISRCTN90744784 https://doi.org/10.1186/ISRCTN90744784

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

Submission date 26/11/2008	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 26/11/2008	**Overall study status** Completed	
Last Edited 08/05/2012	**Condition category** Infections and Infestations	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

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 TCID50 in 0.1 ml)
5. Control group four: one dose of mOPV type 1 (potency 10^6.8 TCID50 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 measure
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

Secondary outcome measures
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

Overall study start date
10/01/2009

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

Age group
Child

Lower age limit
6 Months

Upper age limit
9 Months

Sex
Both

Target number of participants
1000

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 Biotec Limited (India)

Sponsor details
B-1 Extn/G-3
Mohan Co-op. Indl. Estate
Mathura Road
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India
110044
+91 (0)11 4167 8000/9000
aranichatterjee@panaceabiotec.com

Sponsor type
Industry

Website
http://www.panacea-biotec.com/

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
Private sector organisation

Funding Body Subtype
International organizations

Location
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	01/02/2012		Yes	No