

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

☒ Prospectively registered

☐ Protocol

Registration date

26/11/2008

Overall study status

Completed

☐ Statistical analysis plan

☒ Results

Last Edited

08/05/2012

Condition category

Infections and Infestations

☐ 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

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

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Mathura Road
New Dehli
India
110044
+91 (0)11 4167 8000/9000
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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, , BO3, 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