

Comparative evaluation of immunogenicity and reactogenicity of monovalent type 2 and 3 oral poliovirus vaccines (mOPV 2 and mOPV3) versus trivalent oral poliovirus vaccine (tOPV), and bivalent oral poliovirus vaccine (bOPV) versus monovalent types 1 and 3 oral poliovirus vaccines, respectively: a randomised double-blind trial

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

23/08/2011

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

Protocol serial number

RPC273

Study information

Scientific Title

Study objectives

To determine if one or two doses of mOPV2 or mOPV3 induces significantly higher levels of seroconversion against poliovirus types 2 or 3, respectively, than does one or two doses of tOPV to these Sabin strains and to determine if one or two doses of bOPV induces similar seroconversion to types 1 and 3, respectively, compared to one or two doses of mOPV1 or mOPV3. Additionally, at one site (Indore), to determine if one or two doses of mOPV2 or mOPV3 significantly reduces excretion of poliovirus types 2 or 3, respectively than does one or two doses of tOPV and to determine if one or two doses of bOPV significantly reduces excretion of poliovirus type 1 and type 3 than does one or two doses of tOPV.

Ethics approval required

Old ethics approval format

Ethics approval(s)

1. MGM Medical College gave approval on the 7th June 2008 (ref: PBL/CR/0042008/CT)
2. The Drug Controller General of India gave approval on the 11th June 2008 (ref: PBL/CR/0042008/CT)

Study design

Randomised double-blind clinical trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Poliomyelitis

Interventions

1. Control: standard trivalent oral poliovirus vaccine (tOPV) - one or two doses
2. Intervention group one: monovalent type 1 oral poliovirus vaccine (mOPV1) - one or two doses
3. Intervention group two: monovalent type 2 oral poliovirus vaccine (mOPV2) - one or two doses
4. Intervention group three: monovalent type 3 oral poliovirus vaccine (mOPV3) - one or two doses
5. Intervention group four: bivalent type 1 and 3 oral poliovirus vaccine (bOPV) - one or two doses

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Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Oral poliovirus vaccines

Primary outcome(s)

Seroconversion 30 days after a single dose of mOPV2 or mOPV3 compared to tOPV or seroconversion following a single dose of bOPV compared to mOPV1.

Key secondary outcome(s)

1. Seroconversion of two doses of mOPV2 or mOPV3 compared to tOPV
2. Seroconversion of one or two doses of bOPV compared to mOPV1 or mOPV3
3. Prevalence of excretion of poliovirus serotypes 1, 2, and 3 at 7, 30, 37, and 60 days (at Indore site only)

Completion date

13/10/2008

Eligibility**Key inclusion criteria**

1. Healthy newborns (either sex) (greater than or equal to 2.50 kg birth weight, apgar score at 5 min greater than or equal to 9) at the study sites (large maternity hospitals)
2. Residing within a relatively short and easily accessible distance (less than 30 km)
3. Not planning to travel away during entire the study period (birth - 2 months)

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Neonate

Sex

All

Key exclusion criteria

1. Newborns requiring hospitalisation
2. Birth weight below 2.50 kg
3. Apgar score at 5 min less than 9
4. Residence greater than 30 km from study site
5. Families expecting to be absent during the 60-day study period
6. A diagnosis or suspicion of immunodeficiency disorder (either in the participant or in a member of the immediate family) will render the newborn ineligible for the study

Date of first enrolment

13/08/2008

Date of final enrolment

13/10/2008

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

Industry

Funder Name

Panacea Biotec Limited (India)

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?
Results article	results	13/11/2010		Yes	No