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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

Registration date
26/11/2008

Last Edited
23/08/2011

Recruitment status
No longer recruiting

Overall study status
Completed

Condition category
Infections and Infestations

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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
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

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. 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 measure
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.

Secondary outcome measures
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)

Overall study start date
13/08/2008

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

Age group
Neonate

Sex
Both

Target number of participants
900

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 Biotec Limited (India)

Sponsor details
B-1 Extn/G-3
Mohan Co-op. Indl. Estate
Mathura Road
New Delhi
India
110044
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aranichatterjee@panaceabiotec.com

Sponsor type
Industry

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

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
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	13/11/2010		Yes	No