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Comparative evaluation of immunogenicity of Monovalent Type 1 Oral Poliovirus Vaccine (mOPV1) versus trivalent OPV (tOPV): a randomised double-blind trial set in India (Panacea Biotec Ltd mOPV1 study)

Submission date 01/02/2006	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 01/02/2006	**Overall study status** Completed	
Last Edited 17/01/2012	**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
RPC133/Panbio/CR/0982004/CT

Study information

Scientific Title

Study objectives
One dose of mOPV1 induces significantly higher levels of seroconversion against poliovirus type 1 among Indian children in Indore and Hyderabad compared to tOPV.

Please note that as of 18/10/2007 the anticipated end date of this trial was updated from the 31st December 2006 to 28th March 2006.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval received on the 20th October 2005.

Study design
Clinical trial, evaluation based, randomised double blind trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Prevention

Participant information sheet

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

Interventions
Monovalent Type 1 Oral Poliovirus Vaccine (mOPV1) versus Trivalent OPV (tOPV).

Measurements:
1. Cord blood will be collected immediately after birth
2. Blood collection at 30 days of age and stool collection taken
3. During one week follow-up, stool sample collected at day 7

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Monovalent Type 1 Oral Poliovirus Vaccine (mOPV1), Trivalent OPV (tOPV).

Primary outcome measure
Seroconversion after 30 days of a single dose of tOPV or mOPV1 produced for Biofarma bulk.

Secondary outcome measures
1. Prevalence of excretion of Poliovirus type 1 in stool specimens 7 days post-challenge with mOPV1 (age: 30 days + 7 days)
2. Comparison of mOPV1 produced by Biofarma bulk with the mOPV1 produced by Sanofi Pasteur bulk

Overall study start date
25/10/2005

Completion date
28/03/2006

Eligibility

Key inclusion criteria
1. Healthy newborns (greater than or equal to 2.75 kg birth weight, apgar score at 5 minutes, greater than or equal to 9) at the study site(s) (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
600

Key exclusion criteria
1. Newborns requiring hospitalisation
2. Birth weight below 2.75 kg
3. Apgar score at 5 minutes 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
25/10/2005

Date of final enrolment
28/03/2006

Locations

Countries of recruitment
India

Switzerland

Study participating centre
World Health Organization
Geneva-27
Switzerland
CH 1211

Sponsor information

Organisation
Panacea Biotec Ltd (India)

Sponsor details
B-1 Extn. A-27
Mohan Co-op Industrial Estate
Mathura Road
New Delhi
India
110044
arani@pblintranet.com

Sponsor type
Industry

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

ROR
https://ror.org/01ew11x49

Funder(s)

Funder type
Research organisation

Funder Name
Gates Foundation (USA) - grant received for a World Health Organization (WHO) Polio Eradication Initiative

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	05/08/2011		Yes	No