

A phase-IV randomised, double blind comparative evaluation of immunogenicity of Monovalent Type 1 Oral Poliomyelitis Vaccine (mOPV1) versus trivalent OPV (tOPV): four-armed study

Submission date 07/09/2007	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered
Registration date 07/09/2007	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 28/09/2012	Condition category Infections and Infestations	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> 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

RPC241

Study information

Scientific Title

Study objectives

This study aims to demonstrate the superiority of one dose of Monovalent Type 1 Oral Poliomyelitis Vaccine (mOPV1) compared to trivalent Oral Poliomyelitis Vaccine (tOPV).

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethics approval received from:

1. World Health Organization Research Ethics Review Committee (WHO ERC) on the 3rd September 2007 (ref: RPC241)
2. MGM Medical College and Associated Hospital Society Indore on the 7th August 2007
3. Osmania Medical College Koti, Hyderabad on the 10th August 2007

Study design

Clinical trial, interventional, randomised, double blind four-armed comparative study

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

Health condition(s) or problem(s) studied

Polio

Interventions

Control group: 2 drops (approximately 0.1 ml) standard dose tOPV manufactured by Panacea at birth and 30 days of age

Intervention group 1: 2 drops (approximately 0.1 ml) standard potency mOPV1 manufactured by Panacea at birth and 30 days of age

Intervention group 2: 2 drops (approximately 0.1 ml) higher potency mOPV1 manufactured by

Panacea at birth and 30 days of age

Intervention group 3: 2 drops (approximately 0.1 ml) standard dose mOPV1 manufactured by Sanofi Pasteur at birth and 30 days of age

Blood collection at birth (cord blood), further venipuncture blood collection at 30 days and at 60 days.

Contact details for Principal Investigator:

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Intervention Type

Drug

Phase

Phase IV

Drug/device/biological/vaccine name(s)

Monovalent Type 1 Oral Poliomyelitis Vaccine (mOPV1), trivalent Oral Poliomyelitis Vaccine (tOPV).

Primary outcome measure

Seroconversion 30 days after a single dose of tOPV or mOPV1.

Secondary outcome measures

Seroconversion after two doses of vaccine (one of three mOPV1 vaccines and tOPV).

Overall study start date

08/09/2007

Completion date

08/03/2008

Eligibility

Key inclusion criteria

1. Healthy infants (greater than or equal to 2.5 kg birth weight, apgar score at 5 minutes greater than or equal to 9)
2. Born at study sites (maternity hospitals)
3. Residing less than 30 km away from study site
4. Not planning to travel during entire study period (birth to 2 months)

Participant type(s)

Patient

Age group

Child

Sex

Both

Target number of participants

720

Key exclusion criteria

1. Newborns requiring hospitalisation
2. Birth weight less than 2.5 kg
3. Apgar score at 5 minutes less than 9
4. Residence greater than 30 km from study sites
5. Families expecting to be absent during the 60 day study period
6. A diagnosis or suspicion of immunodeficiency disorder (either in participant or immediate family member)

Date of first enrolment

08/09/2007

Date of final enrolment

08/03/2008

Locations**Countries of recruitment**

India

Switzerland

Study participating centre**World Health Organization**

Geneva 27

Switzerland

CH-1211

Sponsor information**Organisation**

Panacea Biotech Limited (India)

Sponsor details

c/o Dr Arani Chatterjee

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New Delhi
India
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+91 (0)11 4167 8000 or 4167 9000
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

Gates Foundation (USA)

Funder Name

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