ISRCTN54186735 https://doi.org/10.1186/ISRCTN54186735

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

Registration date
07/09/2007

Overall study status
Completed

Last Edited
28/09/2012

Condition category
Infections and Infestations

[X] 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

Protocol serial number
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

Study type(s)
Treatment

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.

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

Key secondary outcome(s))
Seroconversion after two doses of vaccine (one of three mOPV1 vaccines and tOPV).

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

Healthy volunteers allowed
No

Age group
Child

Sex
All

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 Biotec Limited (India)

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

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