

Comparative evaluation of Immunogenicity of monovalent type 1 Oral Poliovirus Vaccine (mOPV1) and monovalent type 3 Oral Poliovirus Vaccine (mOPV3) versus trivalent Oral Poliovirus Vaccine (tOPV): a randomised double-blind controlled trial in South Africa

Submission date 15/11/2007	Recruitment status No longer recruiting	☒ Prospectively registered
Registration date 15/11/2007	Overall study status Completed	☐ Protocol
Last Edited 21/02/2012	Condition category Infections and Infestations	☐ Statistical analysis plan
		☒ Results
		☐ Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Roland Sutter

Contact details
World Health Organization
Avenue Appia 20
Geneva-27
Switzerland
CH-1211
+41 (0)22 791 4682
sutterr@who.int

Additional identifiers

Protocol serial number
RPC236

Study information

Scientific Title

Study objectives

The study aims to demonstrate the superiority of one dose of monovalent type 1 Oral Poliovirus Vaccine (mOPV1) or monovalent type 3 Oral Poliovirus Vaccine (mOPV3) compared to trivalent Oral Poliovirus Vaccine (tOPV) in inducing seroconversion.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethics approval received from:

1. World Health Organization (WHO) Ethics Review Committee (ERC) on the 24th October 2007 (ref: RPC236)
2. University of Cape Town's Research Ethics Committee on the 2nd October 2007 (ref: 355 /2007)

Regulatory authority approval from the Medicines Control Council South Africa is still in progress.

Primary study design

Interventional

Study design

Interventional randomised double blind controlled trial for 3 arms of vaccine produced by GSK but randomised and unblinded for the mOPV1 vaccine produced by Panacea Biotec Ltd.

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Poliomyelitis

Interventions

Control group:

2 drops (approximately 0.1 ml) standard dose of tOPV manufactured by GlaxoSmithKline (GSK) at birth.

Intervention groups:

1. 2 drops (approximately 0.1 ml) of mOPV1 manufactured by GSK at birth
2. 2 drops (approximately 0.1 ml) of mOPV1 manufactured by Panacea at birth
3. 2 drops (approximately 0.1 ml) of mOPV3 manufactured by GSK at birth

Blood collection at birth (cord blood or blood from newborn) and at 30 days.

Principal Investigator:

Professor Gregory D. Hussey

Institute of Infectious Disease and Molecular Medicine
University of Cape Town
Anzio Road, Observatory
7925 Cape Town
South Africa
Tel: +27 (0)21 406 6738
Fax: +27 (0)21 406 6081
Email: Gregory.Hussey@uct.ac.za

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Monovalent type 1 Oral Poliovirus Vaccine (mOPV1), monovalent type 3 Oral Poliovirus Vaccine (mOPV3), trivalent Oral Poliovirus Vaccine (tOPV)

Primary outcome(s)

Seroconversion 30 days after a single dose of tOPV, mOPV1, or mOPV3. Measurements on humoral immunity (specific primary endpoints) as follows:

1. One dose of mOPV1 induces significantly higher levels of seroconversion against poliovirus type 1 than one dose of tOPV
2. One dose of mOPV3 induces significantly higher levels of seroconversion against poliovirus type 3 than one dose of tOPV

Key secondary outcome(s)

No secondary outcome measures

Completion date

15/11/2009

Eligibility

Key inclusion criteria

1. Healthy infants (birth weight greater than or equal to 2.5 kg and Apgar score greater than or equal to 9 at 5 minutes) born at study sites
2. Residing less than or equal to 50 km from study sites
3. Family is not planning on travel during the study period (birth to 1 month)

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Neonate

Sex

All

Key exclusion criteria

1. High risk newborns
2. Other newborns requiring hospitalisation
3. Birthweight less than 2.5 kg
4. Apgar score less than 9 at 5 minutes
5. Infants residing more than 50 km from study sites
6. Infants whose families are planning to be absent during one month study period
7. A diagnosis or suspicion of B cell immunodeficiency in participant or immediate family

The study will not collect information on acquired immunodeficiency disease or Human Immunodeficiency Virus (HIV) status of mother or study subject.

Date of first enrolment

15/11/2007

Date of final enrolment

15/11/2009

Locations**Countries of recruitment**

South Africa

Switzerland

Study participating centre**World Health Organization**

Geneva-27

Switzerland

CH-1211

Sponsor information**Organisation**

World Health Organization (WHO) (Switzerland)

ROR

<https://ror.org/01f80g185>

Funder(s)

Funder type

Research organisation

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

Funder Name

Gates Foundation (USA)

Funder Name

International Financing Facility for Immunisations (IFFIm) (UK)

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	15/01/2012		Yes	No