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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

Registration date
15/11/2007

Last Edited
21/02/2012

Recruitment status
No longer recruiting

Overall study status
Completed

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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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.

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.

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet

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.

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

Secondary outcome measures
No secondary outcome measures

Overall study start date
15/11/2007

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

Age group
Neonate

Sex
Both

Target number of participants
800

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 immunodefiency 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)

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Sponsor type
Research organisation

Website
http://www.who.int/en/

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, , BO3, OMS

Funding Body Type
Private sector 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

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	15/01/2012		Yes	No