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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 Egypt

**Submission date**
12/09/2005

**Recruitment status**
No longer recruiting

**Registration date**
01/02/2006

**Overall study status**
Completed

**Last Edited**
17/10/2008

**Condition category**
Infections and Infestations

[_] 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**
RPC 127

## Study information

## Scientific Title

## Study objectives
One dose of monovalent oral poliovirus vaccine induces higher levels of seroconversion against poliovirus type 1 when compared to trivalent oral poliovirus vaccine.

Please note that as of 18/10/2007 the anticipated start and end dates of this trial were modified, the initial trial dates were as follows:
Anticipated start date: 15/07/2005
Anticipated end date: 31/07/2006

## Ethics approval required
Old ethics approval format

## Ethics approval(s)
Ethics approval received on the 28th June 2005.

## Primary study design
Interventional

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

## Study type(s)
Prevention

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

## Interventions
One dose of monovalent oral poliovirus vaccine compared to trivalent oral poliovirus vaccine.

Measurements:
1. Cord blood will be collected immediately after birth
2. 30 days after birth, second sample of blood collected by heel stick method and a stool sample taken
3. Four additional stool samples collected on a weekly basis at 7, 14, 21, and 28 days after birth
4. 60 days after birth, third sample of blood collected by heel stick method

## Intervention Type
Drug

## Phase
Not Specified

## Drug/device/biological/vaccine name(s)
Oral poliovirus

## Primary outcome(s)

To demonstrate the superiority of one dose of mOPV1 compared with tOPV by assessing:
1. Humoral Immunity - one dose of mOPV1 induces significantly higher levels of seroconversion against poliovirus type 1 than does one dose of tOPV
2. Mucosal Immunity - one dose of mOPV1 significantly reduces excretion of poliovirus type 1 after a mOVP1 challenge than following one dose of tOPV

### Key secondary outcome(s)
The secondary endpoint is prevalence of excretion of poliovirus type 1 in stool specimens 7 days post-challenge with mOPV1 at age 30 days + 7 days. Additional endpoints will be prevalence of excretion in 4 weeks after mOPV1 challenge by vaccination group; and seroconversion at 60 days after 2 doses of mOPV1 (no control available).

### Completion date
31/07/2005

## Eligibility

### Key inclusion criteria
1. Infants born healthy (greater than or equal to 2.75 kg, apgar score greater than or equal to 9 at five minutes) at the study site(s) (large maternity hospitals)
2. Residing within a relatively short and easily accessible distance (less than 30 km) in the same governorate as the study site
3. Not planning to travel away during entire the study period (birth to two months)

### Participant type(s)
Patient

### Healthy volunteers allowed
No

### Age group
Neonate

### Sex
All

### Key exclusion criteria
1. High-risk newborns will be excluded
2. Newborns requiring hospitalisation
3. Birth weight below 2.75 kg
4. Apgar score less than 9 at five minutes
5. Residence greater than 30 km from study site (or residing in another governorate)
6. Family is planning to be absent during the 60-day study period
7. 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
15/07/2005

**Date of final enrolment**
31/07/2005

# Locations

**Countries of recruitment**
Egypt

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**
Charity

**Funder Name**
Gates Foundation (USA)

# 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 | 16/10/2008 | | Yes | No |