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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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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.

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

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Prevention

Participant information sheet

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 measure
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

Secondary outcome measures
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).

Overall study start date
15/07/2005

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

Age group
Neonate

Sex
Both

Target number of participants

600

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)

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Sponsor type

Research organisation

Website
http://www.who.int

ROR
https://ror.org/01f80g185

Funder(s)

Funder type
Charity

Funder Name
Gates Foundation (USA)

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	16/10/2008		Yes	No