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A trial to assess the practicality of delivering fractional doses of an inactivated poliovirus vaccine in a community-based campaign in under 5 year-olds in a rural setting in The Gambia

Submission date
12/09/2016

Recruitment status
No longer recruiting

Registration date
14/09/2016

Overall study status
Completed

Last Edited
31/08/2017

Condition category
Infections and Infestations

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol

Background and study aims
Polio is a viral infection that can cause a flu-like illness and in less than 1% of cases causes temporary paralysis. This can sometimes lead to lifelong difficulties, such as permanent paralysis, muscle weakness, shrinking of the muscles, tight joints, and twisted feet or legs. As part of the global effort to eradicate polio through vaccination there is going to be a switch from the oral polio vaccine (OPV) drops to an injected polio vaccine (IPV). Many countries have already made this change and even those countries still using the drops are now also using the injected vaccine. It may be that, in the same way the OPV drops have been given to all children during vaccine campaigns in The Gambia and across West Africa, the IPV vaccine will also need to be given during campaigns. Research in the past, including research in The Gambia, has shown that giving babies only one-fifth of the normal dose as an injection into the skin (an intradermal injection) gives most babies and children protection from polio. Giving a smaller volume in this way means that one normal vaccine dose can be given to five children. This means many millions of children can be vaccinated without the world running short of vaccine. Giving an injection into the skin is more difficult than giving the oral drops. Some different ways have been found to make it easier to give the injection into the skin, and the aim of this study is to find out which of three different methods is better. The study looks at how many babies and children can be vaccinated in each day of a campaign; how long each injection takes; how much training nurses giving the injections need; how much waste each of the methods produces (for example used needles which need to be disposed of carefully); whether any babies or children have a reaction to the vaccine (like a temperature or some redness where the injection is given); which method mothers and father think is better; which method the nurses giving the vaccine think is easier; and how much protection from polio each method provides.

Who can participate?
Children between four months and five years of age

What does the study involve?
Information is collected about the children from their Infant Welfare Cards, including how old they are and the vaccines they have had. Children who are two years old or more also have a blood test. On the day of the campaign participants are invited back to a vaccination point in the community. The children are randomly allocated to receive a polio vaccine injection into the skin using one of three different methods. This should only take a few minutes. Three days later a member of the study team visits the children at home to ask some questions and look at the site on the child's arm where the injection was given. They also check the child's temperature. If the child is unwell in the four weeks after this the team provides any treatment that is needed. After four weeks those children aged over 2 years who had a blood test the first time have a second blood test. The blood tests measure the amount of protection from polio the child has. All parents are contacted at this point to see that their children are well.

What are the possible benefits and risks of participating?
The study is being carried out with the World Health Organisation and is expected to influence the way vaccine campaigns run in many parts of the world in the future. Babies and children in the study will get an extra dose of the injected polio vaccine. This is likely to increase the amount of protection they have from polio. Giving the injection is likely to hurt briefly and may make the child cry like other injections they have had in the past. Although it is very rare, some children can have a reaction to an injection like this. If a reaction does occur babies and children will receive the treatment they need. Taking a blood test will also hurt and may cause a small bruise but does not cause any problems. The study team will come back to the community to tell them the results of the study although individual results cannot be provided.

Where is the study run from?
MRC Unit The Gambia

When is the study starting and how long is it expected to run for?
May 2016 to January 2017

Who is funding the study?
World Health Organization (Switzerland)

Who is the main contact?
Dr Ed Clarke
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Contact information

Type(s)
Public

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Additional identifiers

Protocol serial number
SCC1495

Study information

Scientific Title
A pragmatic trial to quantitatively and qualitatively assess different techniques for the intradermal administration of fractional dose inactivated poliovirus vaccine in a campaign setting in The Gambia

Study objectives
A pragmatic trial will be undertaken to compare the utility of three different methods of intradermal fractional dose inactivated poliovirus vaccine administration to children under 5 years of age in a rural community-based campaign setting in The Gambia.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. The Gambia Government/MRC Joint Ethics Committee, 16/08/2016, ref: SCC1495
2. The WHO Research Ethics Committee, 12/07/2016, ref: ERC.0002776

Study design
Single-centre pragmatic randomized open-label trial with allocation concealment

Primary study design
Interventional

Study type(s)
Prevention

Health condition(s) or problem(s) studied
Poliomyelitis

Interventions
The trial is pragmatic in aiming to provide data which will reflect the future use of ID fIPV in campaign and cVDPV type 2 outbreak control. Under such circumstances, the vaccine will be offered universally within the target age group. In addition, when considering the induction of seroprotection against poliovirus, the administration of ID fIPV is of proven benefit and the intervention is of minimal risk beyond the risks associated with any routine vaccination. For these reasons the eligibility criteria are intentionally inclusive.

Arm 1: 0.1 ml inactivated poliovirus vaccine (IPV) administered as a single dose intradermally by needle and syringe
Arm 2: 0.1 ml inactivated poliovirus vaccine (IPV) administered as a single dose intradermally by needle and syringe with an Intradermal adaptor (West)
Arm 3: 0.1 ml inactivated poliovirus vaccine (IPV) administered as a single dose intradermally using a disposable syringe jet injector (Tropis, Pharmajet)

Three days later a member of the study team visits the children at home to ask some questions and look at the site on the child's arm where the injection was given. They also check the child's temperature. If the child is unwell in the four weeks after this the team provides any treatment that is needed. After four weeks those children aged over 2 years who had a blood test the first time have a second blood test. The blood tests measure the amount of protection from polio the child has. All parents are contacted at this point to see that their children are well.

Intervention Type
Biological/Vaccine

Primary outcome(s)
1. Total time taken to deliver ID fIPV using each of the three methods of administration; also sub-divided into key components of the procedure (e.g. injection preparation, infant or child preparation, injection delivery)
2. Number of ID fIPV doses delivered using each of the three methods in the course of a defined campaign day by one vaccination team
3. Qualitative measures of administration method utility including training requirements as collected through structured questionnaires and through focus groups (data collected separately for vaccinators and the parents/guardians of vaccinated infants and children)
4. Local and systemic reactogenicity on day 3 following ID fIPV. Home visits conducted by trained field staff. Data collected according to standardized proforma
5. Serious adverse events (SAE) and adverse events (AE) in the 4 weeks following ID fIPV administration
6. Semi-quantitative measure of distress in infants and children associated with ID fIPV administration
7. Storage volumes and weights of equipment required for ID fIPV delivery and subsequent bio-waste disposal including any differences the equipment required to safely deliver such vaccinations in a campaign
8. Number of ID fIPV doses deliverable per IPV vial using each of the three administration methods (to identify any wastage associated with syringe/device filling)
9. Immune response to ID fIPV measured using polio neutralization assays conducted by the CDC, USA, at 4 to 6 weeks after the campaign
10. Changes in both the time taken to deliver the ID fIPV and in the immune responses generated over the course of a 3-day campaign (to identify the number of doses administered before each of these elements are achieved optimally for each of the given ID fIPV administration methods)
11. Changes in the vaccine vial monitors (VVM) and also temperature deviations identified using a continuous temperature data logger associated with a campaign using each of the three administration methods
12. Qualitative factors which might influence campaign uptake in The Gambia and comparable sub-Saharan African settings (data collected from public health officers, regional health and EPI personnel as well as from the parents/guardians of vaccinated infants and children and other community leaders and community members)

Key secondary outcome(s))
N/A

Completion date
31/01/2017

Eligibility

Key inclusion criteria
1. Written or thumb-printed informed consent obtained from a child's parent or guardian
2. Resident within the geographical area which is expected to be covered by the campaign
3. Between 4 and 59 months of age at the time of the campaign

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group
Child

Lower age limit
4 months

Upper age limit
59 months

Sex
All

Key exclusion criteria
1. Anaphylaxis or a severe, potentially life threatening, allergic reaction to a previous vaccination
2. Any other condition or significant acute illness meaning that it is judged to be against the infant's or child's best interests to receive ID fIPV (note that most chronic illnesses and minor acute illnesses - when normal vaccinations would be encouraged, do not represent exclusions for the trial)

Date of first enrolment
15/10/2016

Date of final enrolment
30/11/2016

Locations

Countries of recruitment
Gambia

Study participating centre
MRC Unit The Gambia
PO Box 273
Banjul
Gambia
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Sponsor information

Organisation
MRC Unit The Gambia

ROR
https://ror.org/025wfj672

Funder(s)

Funder type
Other

Funder Name
World Health Organization

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

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes