ClinicalTrials.gov PRS DRAFT Receipt (Working Version)
Last Update: 08/10/2018 04:05

ClinicalTrials.gov ID: [Not yet assigned]

## Study Identification

| | |
|---|---|
| Unique Protocol ID: | 201518502-C ( bOPV-PRO-C ) |
| Brief Title: | Trail To Evaluate the Immune Effects of Primary and Booster Immunizations With Poliovirus Vaccine |
| Official Title: | Trail To Evaluate the Immunity Duration of Different Sequential Immunization Schedules and Effectiveness for Bivalent Oral Poliomyelitis Vaccine Co-administered With IPV Booster Immunization for Poliovirus Vaccine |
| Secondary IDs: | |

## Study Status

| | |
|---|---|
| Record Verification: | May 2018 |
| Overall Status: | Recruiting |
| Study Start: | January 4, 2018 [Actual] |
| Primary Completion: | May 2020 [Anticipated] |
| Study Completion: | August 2020 [Anticipated] |

## Sponsor/Collaborators

| | |
|---|---|
| Sponsor: | Chinese Academy of Medical Sciences |
| Responsible Party: | Principal Investigator<br>Investigator: Jingsi Yang [jiyang]<br>Official Title: Senior<br>Affiliation: Chinese Academy of Medical Sciences |
| Collaborators: | Guangxi Center for Disease Control and Prevention |

## Oversight

| | |
|---|---|
| U.S. FDA-regulated Drug: | No |
| U.S. FDA-regulated Device: | No |
| U.S. FDA IND/IDE: | No |
| Human Subjects Review: | Board Status: Approved<br>Approval Number: GXIRB2017-0009-2<br>Board Name: GUANXI IRB<br>Board Affiliation: Guangxi Province Centers for Disease Control and Prevention<br>Phone: +867712518979<br>Email: mozhj@126.com<br>Address: |

18# Jinzhou Road, Nanning, Guangxi Province

Data Monitoring: Yes

FDA Regulated Intervention: No

## Study Description

Brief Summary: Trail To Evaluate the Immunity Duration of healthy children who already took part in " The safety and immunogenicity by different sequential schedules of bOPV and bOPV in dragee candy with sIPV, a randomized, double blind, single center and parallel phase III clinic trial was performed in Infants of two-month old in Guangxi Province, China" and continue to search for the effects of booster immunization.

Detailed Description: According to the requirement of the Strategy of Polio Eradication & Endgame Strategic Plan 2013-2018, bivalent oral attenuated live poliomyelitis vaccine against type 1 and 3 (bOPV) and inactivated poliomyelitis vaccine made by Sabin strain (sIPV) need to be used to eradiation both the wild poliovirus and vaccine-derived poliovirus. To evaluate the safety and immunogenicity by different sequential immunization schedules of bOPV and bOPV in dragee candy with sIPV,a randomized, double blind, single center and parallel phase III clinic trial was performed in Guangxi Province in China. A total of 1200 infants at 2 months old were selected, and randomlydivided into 12 different groups (100 individuals were included in each group) administrated the vaccines at 0, 28, 56 days schedule.The detail of each group as following:1)1-dose cIPV + 2-dose bOPV (Candy); 2)1-dose sIPV + 2-dose bOPV (Candy); 3)2-dose cIPV + 1-dose bOPV (Candy); 4)2-dose sIPV + 1-dose bOPV (Candy); 5)2-dose cIPV + 1-dose tOPV (Candy); 6)2-dose sIPV + 1-dose tOPV (Candy); 7)1-dose cIPV + 2-dose bOPV (Liquid); 8)1-dose sIPV + 2-dose bOPV (Liquid); 9)2-dose cIPV + 1-dose bOPV (Liquid); 10)2-dose sIPV + 1-dose bOPV (Liquid); 11)2-dose cIPV + 1-dose tOPV (Liquid); 12)2-dose sIPV + 1-dose tOPV (Liquid).Blood Sample was collected before vaccination and one month after the third dose of vaccination. Neutralization antibody against type I, Type I and Type III poliomyelitis virus were detected to evaluate the seroprotection rates and antibody geometric mean concentrations. The fecal samples were collected to test viral shedding.The safety by different sequential schedule of the vaccines was also evaluated.This part of study have already been done in 2016.

To further evaluate the immunity duration of different sequential immunization schedules for bOPV and IPV ,more importantly,trying to research the effectiveness of bOPV booster immunization,the previous study will continue.

The detail of the research as following:

The subject will been recruited again,all subjects have already took part in phase 3 clinical trail in Guangxi ,vaccinated 3-dose primary immunization with polio vaccines and with the result of the paired serum .In order to evaluate the immune effects of primary immunizations with poliovirus vaccine(3 doses of immunization ). Blood samples were collected when the subject aged 24 months old,36 months old and 48 months old. Neutralization antibody against type I, Type I and Type III poliomyelitis virus were detected to evaluate the positive rate and antibody geometric mean titers.

In order to research the effectiveness of bOPV booster immunization, when subjects aged 48 months,they should take 1-dose bOPV(liquid/candy ) as boosting immunization.The vaccine producer and vaccine dosage form of bOPV should same with primary vaccination .If bOPV(candy/liquid) is not available ,in order to protect the rights and interests of subjects ,the investigator can adjust other poliovirus vaccine such as IPV replace bOPV.

The anticoagulant blood collected from subjects aged 48 months and the 28 days after booster immunization will been used to detect cellular immunity situation.

## Conditions

Conditions: Poliomyelitis

Keywords: bOPV, IPV, Immunity Duration,Booster Immunization

## Study Design

Study Type: Interventional

Primary Purpose: Prevention

Study Phase: Phase 3

Interventional Study Model: Parallel Assignment

Number of Arms: 3

Masking: Quadruple (Participant, Care Provider, Investigator, Outcomes Assessor)

Allocation: Non-Randomized

Enrollment: 1165 [Anticipated]

## Arms and Interventions

| Arms | Assigned Interventions |
|---|---|
| Experimental: bOPV(Candy)<br>bOPV (Candy): bivalent oral attenuated live poliomyelitis vaccine against type 1 and type 3 in Dragee Candy (Human Diploid Cell) Produced by Institute of Medical Biology, Chinese Academy of Medical Sciences.<br>1g/pill,10 pills/pach,one pill each time; each pill containing polio virus≥5.92 lgCCID50 including type1 polio virus≥5.8 lgCCID50，type 3 polio virus ≥5.3lgCCID50. | Biological/Vaccine: bOPV(Candy)<br>A single dose of 1 pill orally of bOPV to subjects aged 48 months who recieved bOPV (candy) produced by institute of Medical Biology, Chinese Academy of Medical Sciences in primary immunization. If bOPV(candy/liquid) is not available ,in order to protect the rights and interests of subjects ,the investigator can adjust other poliovirus vaccine such as IPV replace bOPV. |
| Experimental: bOPV(Liquid)<br>bOPV (Liquid): bivalent oral attenuated live poliomyelitis vaccine against type 1 and type 3 (Human Diploid Cell) Produced by Institute of Medical Biology, Chinese Academy of Medical Sciences.<br>0.5ml or 1.0ml each bottle;total content of polio virus≥7.12lgCCID50/ml，type1 polio virus≥7.0 lgCCID50/ml，type 3 polio virus ≥6.5lgCCID50/ml. (2 drops each person;be be equivalent to 0.1ml each person ) | Biological/Vaccine: bOPV(Liquid)<br>A single dose of 2 drops (0.1 ml) orally of bOPV to subjects aged 48 months who recieved bOPV (liquid) produced by institute of Medical Biology, Chinese Academy of Medical Sciences in primary immunization. If bOPV(candy/liquid) is not available,in order to protect the rights and interests of subjects ,the investigator can adjust other poliovirus vaccine such as IPV replace bOPV. |
| Experimental: bOPV ( liquid )<br>bOPV(Liquid):Poliomyelitis (Live) Vaccine Type I Type III (Human Diploid Cell), Oral Produced by Beijing Tiantan Biological Products Co., Ltd. 1.0ml each bottle,2 drops each person(be be equivalent to 0.1ml each person).(total content of polio virus≥6.12lgCCID50，type1 polio virus≥6.0 | Biological/Vaccine: bOPV(Liquid)<br>A single dose of 2 drops (0.1 ml) orally of bOPV to subjects aged 48 months who received tOPV (liquid) produced by Beijing Tiantan Biological Products Co., Ltd. in primary immunization. If bOPV(candy/liquid) is not available,in order to protect the rights and interests |

| Arms | Assigned Interventions |
|---|---|
| lgCCID50，type 3 polio virus ≥5.5lgCCID50 in each 0.1 ml) | of subjects ,the investigator can adjust other poliovirus vaccine such as IPV replace bOPV. |

NOTE : More than one Intervention has the name 'bOPV(Liquid)'

## Outcome Measures

Primary Outcome Measure:

1. Evaluate the effectiveness bOPV(candy/liquid ) co-administered with IPV.
   To evaluate the effectiveness of bivalent oral attenuated live poliomyelitis vaccine against type 1 and type 3 (Human Diploid Cell) (candy/liquid) co-administered with IPV by neutralization assay. Defined ≥ 8 (1/dil) for anti-Poliovirus as positive.

   [Time Frame: at aged 24、36、48 months]

Secondary Outcome Measure:

2. The duration of anti-poliovirus antibodies level.
   Using the neutralization assay to research the duration of anti-poliovirus antibodies types1, 2, and 3 of bivalent oral attenuated live poliomyelitis vaccine against type 1 and type 3 (Human Diploid Cell) (candy/liquid) co-administered with IPV.

   [Time Frame: at aged 24、36、48 months]
3. The adverse reaction and event of EV71 vaccine occur in subjects
   Local and systemic adverse events were active collected in subjects after boosting dose of bOPV.

   [Time Frame: following 28 days after the boosting dose of bOPV]
4. Rationality of booster immunization
   Give one dose boosting vaccine ( bOPV ) when the subject aged 48 months.The type of bOPV (liquid/candy) depends on what kind of vaccine the child had eaten in" Randomized, Double Blind, Single Center, Parallel Trial to Evaluate the Safety and Immunogenicity by Different Sequential Immunization Schedules of Bivalent Oral Poliomyelitis Vaccine Co-administered With IPV in Infants Aged 2 Months."

   [Time Frame: at aged 48 months and 28 days after the boosting dose of bOPV]

## Eligibility

| | |
|---|---|
| Minimum Age: | 24 Months |
| Maximum Age: | 48 Months |
| Sex: | All |
| Gender Based: | No |
| Accepts Healthy Volunteers: | Yes |
| Criteria: | Inclusion Criteria: |

- Subjects who have already took part in phase 3 clinical trail in Guangxi and was vaccinated 3-dose primary immunization with polio vaccines .Moreover，the results of the selected paired serum are required.
- 24 months old(calendar month).
- Guardians understand the contents and requirements of this trail , meanwhile, voluntarily joined this study with informed consents.
- Able to attend all scheduled visits and to comply with all trial procedures(including vaccinate and blood collection)

Exclusion Criteria:

- Any booster immunization with polio vaccine after finishing 3-dose primary immunizations research.
- Polio virus infection was demonstrated in laboratory experiment.
- Participation in another clinical trial at the same times.
- Any condition that in the opinion of the investigator, may interfere with the evaluation of study objectives or increase the risk of subjects,such as acute or chronic diseases 、 some abnormal detected by lab,and so on.

## Contacts/Locations


Central Contact Person: Jingsi Yang, Master
Telephone: +8687168334986
Email: yjs@imbcams.com.cn

Central Contact Backup: Jing Li, Master
Telephone: 13888865251
Email: sola@imbcams.com.cn

Study Officials: Zhaojun Mo, Master
Study Principal Investigator
Guangxi Province Center for Diseases Control and Prevention


Locations: China, Guangxi
Guangxi Provincial Center for Diseases Control and Prevention
[Recruiting]
Nanning, Guangxi, China
Contact: Zhaojun Mo, Master
Principal Investigator: Zhaojun Mo, Master

## IPDSharing

Plan to Share IPD:

## References

Citations:

Links:

Available IPD/Information: