Mother - Daughter Initiative (MDI) in Cervical Cancer Prevention (MDI)

ClinicalTrials.gov Identifier: NCT01096134

Recruitment Status : Completed
First Posted : March 30, 2010
Last Update Posted : October 12, 2015

Sponsor:
Jhpiego

Collaborator:
Merck Sharp & Dohme Corp.

Information provided by (Responsible Party):
Sharon Kibwana, Jhpiego

Study Description

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Brief Summary:
The Mother-Daughter Initiative (MDI) will test the feasibility and acceptability of a strategy to deliver comprehensive cervical cancer prevention services in Thailand and the Philippines by integrating the HPV vaccine for girls ages 9-13 into already successful screening and treatment programs for mothers.

Condition or disease	Intervention/treatment	Phase
Cervical Cancer	Biological: HPV Vaccine (Gardasil)	Not Applicable

Study Design

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Study Type :	Interventional (Clinical Trial)
Actual Enrollment :	8000 participants
Intervention Model:	Single Group Assignment
Masking:	None (Open Label)
Primary Purpose:	Prevention
Official Title:	Mother - Daughter Initiative (MDI) in Cervical Cancer Prevention
Study Start Date :	January 2011
Actual Primary Completion Date :	November 2012
Actual Study Completion Date :	November 2012

Resource links provided by the National Library of Medicine

MedlinePlus related topics: Cervical Cancer

U.S. FDA Resources

Arms and Interventions

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Arm	Intervention/treatment
Experimental: HPV Vaccine Eligible girls were offered 3 doses of the HPV vaccine	Biological: HPV Vaccine (Gardasil) HPV Vaccine Administration: According to the CDC, Gardasil should be delivered through a series of three intra-muscular injections over a six-month period. The second and third doses should be given two and six months after the first dose. The vaccine can be administered at the same visit as other age-appropriate vaccines, such as Tdap, Td, MCV4, influenza, and hepatitis B vaccines. Providers should consider a 15-minute waiting period for vaccine recipients following vaccination. FDA's Approval of Gardasil (June 8, 2006) lists the following information on product Formulation: Each 0.5 mL dose of the vaccine contains: 20 mcg of HPV 6 L1 protein 40 mcg of HPV 11 L1 protein 40 mcg of HPV 16 L1 protein 20 mcg of HPV 18 L1 protein 225 mcg aluminum (as amorphous aluminum hydroxyphosphate sulfate adjuvant) 9.56 mg of sodium chloride 0.78 mg of L-histidine 50 mcg of polysorbate 80 35 mcg of sodium borate water for injection

Outcome Measures

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Primary Outcome Measures :

1. Determine the population coverage of HPV vaccination of girls aged 9-13 offered within the context of cervical cancer screening and treatment of mothers [Time Frame: 18 months]

   The aim of the study to assess whether we can fully vaccinate (all 3 doses),50% of girls aged 9 -13 in the participating districts, in an 18-month period. This corresponds to 4000 girls in Thailand and 4000 in Phillipines. The study will seek to undertand if this level of population coverage (50%), can be achieved through encouraging women that recive cervical cancer screening to bring in their daughters or relatives for vaccination.

Secondary Outcome Measures :

1. Assess mothers' acceptability of having their daughters receive the full course of HPV vaccine after mothers receive screening and treatment services for cervical pre-cancer [Time Frame: 1 year]

   Data on mothers knowledge of the vaccine, and intention to have their daughters vaccinated will be collected for a period of 1 year (or when the target number of 700 women/guardians is reached, whatever comes first).

   Data will be collected on:

   - Proportion of women with daughters who intend to vaccinate their daughters.
   - Proportion of daughters of screened mothers who return to receive the vaccine.
   - Proportion of girls who receive the first vaccine dose and are brought to the facility by a guardian/mother who did NOT recieve cervical cancer screening

2. Inform future programs that aim to introduce the HPV vaccine in the context of secondary screening for cervical cancer by determining the factors related to screened women bringing daughters for HPV vaccination and the costs of vaccine introduction [Time Frame: 2 years]

   Programmatic data will be collected for the duration of the project, including but not limited to:

   - Cost required to implement the program
   - Logistics required to ensure supply and appropriate maintenance of vaccine
   - Human resources required to effectively adminster the vaccine as part of routine services.
   - Key communication and outreach messages that effectively educate the community

Eligibility Criteria

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Information from the National Library of Medicine NIH NLM

Choosing to participate in a study is an important personal decision. Talk with your doctor and family members or friends about deciding to join a study. To learn more about this study, you or your doctor may contact the study research staff using the contacts provided below. For general information, Learn About Clinical Studies.

Ages Eligible for Study:	9 Years to 13 Years (Child)
Sexes Eligible for Study:	Female
Accepts Healthy Volunteers:	Yes

Criteria

Inclusion Criteria:

- Age 9-13 at first HPV vaccine dose
- Mother/legal guardian and daughter are both interested and willing to have the girl receive the HPV vaccine
- Mother/legal guardian and daughter both indicate that they would be able to return to clinic for the three vaccine doses

Exclusion Criteria:

- Girls with a known history of any allergies or severe reaction to any vaccines, food or medicine
- Pregnant adolescents will be excluded. If a girl becomes pregnant after the first dose is administered, she will not be provided with the second or third dose
- Girls with moderate or severe illnesses will be asked to postpone vaccination eg. Pneumonia.
- Girls with a weakened immune system, cancer, leukemia, AIDS or other immune system problems
- Girls with a bleeding disorder or currently taking anticoagulants
- Girls that have received any other vaccinations in the past 4 weeks
- Girls currently on steroids, such as cortisone, prednisone, or anti-cancer drug.

Contacts and Locations

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Information from the National Library of Medicine

To learn more about this study, you or your doctor may contact the study research staff using the contact information provided by the sponsor.

Please refer to this study by its ClinicalTrials.gov identifier (NCT number): ***NCT01096134***

Locations

Philippines

Minglanilla
Cebu, Philippines

Los Banos
Quezon, Philippines

Pagbilao Health Center
Quezon, Philippines

Thailand

Health promotion Clinic Number 11
Nakhon Si Thammarat, Nakisron, Thailand

Ban Pak Poon Health Center
Nakhon Si Thammarat, Nakornsri, Thailand

Maharat Nakhonsithammarat Primary Care Unit
Nakhon Si Thammarat, Nakornsri, Thailand

Pak-Panung District Health Center
Nakhon Si Thammarat, Nakornsri, Thailand

Ban Yuanlae District Health Center
Ban Phon Ko, Thailand

Ban Mai Daeng
Nakhon Si Thammarat, Nakornsri, Thailand

Ban Pai Ta Health Center
Nakhon Si Thammarat, Nakornsri, Thailand

Sponsors and Collaborators

Jhpiego

Merck Sharp & Dohme Corp.

Investigators

Principal Investigator:	Cecilia Llave, MD	Cancer Institute Foundation, Phillipines
Principal Investigator:	Kobchitt Limpaphayom, MD	Chulalongkorn University, Thailand
Principal Investigator:	Enriquito Lu, MD, MPH	Jhpiego

More Information

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Responsible Party:	Sharon Kibwana, Senior Program Officer, Jhpiego
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Other Study ID Numbers:	36448
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Additional relevant MeSH terms:

Uterine Cervical Neoplasms	Uterine Cervical Diseases
Uterine Neoplasms	Uterine Diseases
Genital Neoplasms, Female	Genital Diseases, Female
Urogenital Neoplasms	Vaccines
Neoplasms by Site	Immunologic Factors
Neoplasms	Physiological Effects of Drugs