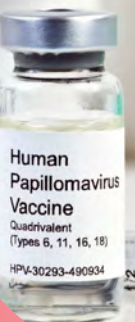




KENSHE

Preventing Cervical Cancer



INTRODUCTION

CERVICAL CANCER is one of the most common types of cancers worldwide and is the leading cause of new cancer cases among women in Africa.



about
the
**KEN
SHE**
study



IN KENYA, about 2,500 women die from this condition each year.

CERVICAL CANCER is caused by an infection with Human papillomavirus, also called **HPV**.

There are vaccines that can prevent **HPV** infections and, therefore, cervical cancer. These vaccines are highly effective and safe.

While **KENYA** has plans to roll out HPV vaccination for 9-10-year-old girls, and the Global Alliance for Vaccines and Immunization (GAVI) supports vaccination to age 14 years, a gap exists in prevention strategies for young women age 15-20 years.

The primary challenge to vaccinating this age group is the cost associated with a 2 dose vaccines schedule. Reducing the vaccine dose to one could address this barrier.

This study is conducted by Kenya Medical Research Institute (KEMRI) sites, based in Kisumu, Thika and Nairobi and the University of Washington, Seattle, USA.

The purpose of the study is to learn whether one dose of HPV vaccine is effective in preventing HPV infection in adolescents aged 15-20 years old. Previous studies done in other countries have found that a single dose of HPV vaccine worked just as well as two doses in preventing HPV. Our study will confirm these findings using a gold-standard study design

The study will enroll 2,250 young women, aged 15- 20 years, and be conducted at three sites in Kenya: 1) NorthEast of Nairobi, 2) Thika, a town in Kiambu County , and 3) Kisumu, in western Kenya.

Two commercial, FDA-approved HPV vaccines will be used in this study. Both HPV vaccines are licensed products with extensive safety data. Adverse events related to HPV and MenVeo vaccination are rare.

Enrollment is anticipated to take 12 months, with 36 months of follow-up for each participant. The entire study duration is 60 months.

WHAT THE STUDY HOPES TO FIND

Preliminary evidence from other studies conducted in Costa Rica and India suggest a single-dose of the HPV vaccine would be over 95% effective in preventing lasting HPV infection. The results of this study will demonstrate whether the single-dose HPV vaccine would be effective in preventing lasting HPV infection among 15-20 year-old women in Kenya.



Using a single dose will lower the cost of providing HPV Vaccination (compared to two doses) and will make it possible for more women to receive the vaccination and be protected from cervical cancer.

QUICK FACTS ABOUT THIS STUDY

Title of Project: Single-dose HPV catch-up vaccination efficacy: A blinded, randomized study of single-dose HPV vaccination among adolescent girls and young women in Kenya

Study Name: KENya Single-dose HPV vaccine Efficacy - The Ken SHe Study

Funding Agency: Bill and Melinda Gates Foundation (OPP1188693)

Sample Size: Up to 2,250

Study Population: Adolescent girls and young women age 15-20 years old

Study Sites: 1) Nairobi, 2) Thika, and 3) Kisumu, Kenya

Follow-up Duration: 36 months from vaccination

Overall Study Duration: 60 months (2018-2023)





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W
UNIVERSITY of
WASHINGTON

FOR MORE INFORMATION CONTACT:

KENYA Medical Research
Institute (KEMRI)


THIKA

Dr. Nelly R Mugo,
Principal Investigator

 +254 723-914-057

KISUMU

Prof. Elizabeth Bukusi Site,
Principal Investigator

 +254 572023779

THIKA

Dr. Nelly R Mugo,
Principal Investigator

 +254 723-914-057

KISUMU

Prof. Elizabeth Bukusi Site,
Principal Investigator

 +254 572023779



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