

An Investigational HPV Vaccine Given Concomitantly with Routine Vaccines

The Disease

- Human papillomavirus (HPV) infection causes benign and malignant disease, including cervical cancers and pre-cancers, anal, vulvar and vaginal cancers, genital warts as well as mouth and throat cancers.
- Nearly 100% of cervical cancers are caused by HPV infection.
- 500,000 new cases of cervical cancer are diagnosed each year worldwide and more than 270,000 annual deaths are attributable to cervical cancer.

The Vaccine

- HPV study vaccine –Includes 5 additional types of HPV in addition to the 4 original types 6, 11, 16, 18, 31, 33, 45, 52 and 58.
- Not a live virus vaccine. It is not capable of causing HPV infection.
- Vaccine is administered as a 3 dose series at Day 1, Month 2, and Month 6.

The Study

- To see if the HPV study vaccine is tolerated and if it works given together or separately with Menactra™ (meningitis vaccine) and Adacel™ (Whooping cough, tetanus, diphtheria booster vaccine) .
- Duration of the study is about 7 months. There are 5 study visits depending on randomization.
- Your child will have equal chance to be in one of 2 groups.
- Group 1 - HPV study vaccine, Menactra and Adacel at Day 1.
- Group 2 – HPV study vaccine at Day 1, Menactra and Adacel at Month 1.
- Both groups get Dose 2 and 3 of the HPV vaccine at Month 2 and Month 6.
- 3-4 total blood draws.
- 5 total injections. 3 HPV injections, 1 Menactra injection, and 1 Adacel injection.
- Urine pregnancy tests on all female subjects at Day 1, Month 1, Month 2, Month 6 and Month 7.

Inclusion Requirements

- Healthy adolescent males and females age 11- 15 years (has not attained 16th birthday) at first vaccination.
- Received routine immunizations for diphtheria, tetanus and pertussis according to the recommended vaccination schedule.
- Abstinent or use of adequate contraceptive precautions.

Exclusion Requirements (Some, but not all)

- Administration of DTP (diphtheria, tetanus and pertussis) or Td (tetanus) booster within the last 5 years.
- Known allergy or contraindication to Adacel or Menactra
- Cannot be in a current study.
- Subject has donated blood within 1 week prior to Day 1 vaccination, or intends to donate during study.
- Prior meningococcal or HPV vaccination or plans to receive other HPV vaccine during study.
- Inactivated vaccines within 14 days prior to vaccination, Live vaccines within 21 days of vaccination
- Oral temperature greater than 100°F within 24 hours prior to enrollment.
- Pregnancy.

Compensation

- Participants will be compensated for time and travel.