Record 1 of 1

Completed

Effectiveness, Safety and Immunogenicity of GSK Biologicals' HPV Vaccine GSK580299 (Cervarix) Administered in Healthy Adolescents

ClinicalTrials.gov ID NCT00534638

Sponsor GlaxoSmithKline

Information provided by GlaxoSmithKline (Responsible Party)

Last Update Posted 2019-11-15

Study Details Tab

Study Overview

Brief Summary

Genital infections with oncogenic human papillomaviruses (HPV) are common in both men and women. The most important disease associated with oncogenic HPV infection is cervical cancer, currently the second leading cause of cancer-related death among women globally. The current study is designed to evaluate the overall impact of HPV immunization in adolescents 12-15 years of age.

Official Title

Evaluation of the Effectiveness of Two Vaccination Strategies Using GlaxoSmithKline Biologicals' HP Vaccine GSK580299 (Cervarix) Administered in Healthy Adolescents

Conditions

Infections, Papillomavirus

Intervention / Treatment

- Biological: Cervarix
- Biological: Engerix-B

Other Study ID Numbers

- 106636
- 2007-001731-55 (EudraCT Number)

Study Start (Actual)

2007-10-04

Primary Completion (Actual)

2014-12-17

Study Completion (Actual)

2014-12-17

Enrollment (Actual)

34412

Study Type

Interventional

Phase

Phase 4

Resource links provided by the National Library of Medicine

MedlinePlus (https://medlineplus.gov/) related topics: Cervical Cancer (https://medlineplus.gov/cervicalcancer.html) HPV (https://medlineplus.gov/hpv.html)

Drug Information (https://dailymed.nlm.nih.gov/dailymed/) available for: Hepatitis B Virus Subtype ADW2 HBsAg Surface Protein Antigen (https://dailymed.nlm.nih.gov/dailymed/search.cfm?labeltype=human&query=Hepatitis+B+Virus+Subtype+ADW2+HBsAg+Surface+Protein+Antigen)

FDA Drug and Device Resources (https://clinicaltrials.gov/fda-links)

Contacts and Locations

This section provides contact details for people who can answer questions about joining this study, and information on where this study is taking place.

To learn more, please see the Contacts and Locations section in How to Read a Study Record (https://clinicaltrials.gov/study-basics/how-to-read-study-record#contacts-and-locations).

This study has 6 locations

Finland

- **Kotka, Finland, 48100**
  GSK Investigational Site
- **Kuopio, Finland, 70100**
  GSK Investigational Site
- **Lahti, Finland, 15110**
  GSK Investigational Site
- **Rauma, Finland, 26100**
  GSK Investigational Site
- **Tampere, Finland, 33100**
  GSK Investigational Site
- **Turku, Finland, 20100**
  GSK Investigational Site

Participation Criteria

Researchers look for people who fit a certain description, called eligibility criteria. Some examples of these criteria are a person's general health condition or prior treatments.

For general information about clinical research, read Learn About Studies (https://clinicaltrials.gov/study-basics/learn-about-studies).

Eligibility Criteria

Description

Inclusion Criteria:

- Study participants who the investigator or delegate believes that they and/or their parents/legally acceptable representative can and will comply with the requirements of the protocol (e.g. completion of the diary cards, return for follow-up visits) should be enrolled in the study.
- A male or female between, and including, 12 and 15 years of age at the time of the first vaccination.

A written informed assent must be obtained from all study participants prior to enrolment. In addition, a written informed consent must be obtained from the study participants' parent or legally acceptable representative.

Note: As according to the Finnish law legal age of consent is 15 years, a written informed consent form can be obtained from study participants aged 15 years old and their parent(s)/legally acceptable representative(s) will receive a letter informing them of their child participation to the study.

- Healthy male and female study participants as established by medical history before entering into the study. If needed, a history-directed clinical examination will be performed by the investigator or delegate (e.g. study nurse).
- Study participants must not be pregnant. Absence of pregnancy should be verified (e.g. urine pregnancy test) as per investigator's or delegate's clinical judgement.
- If the study participant is female, she must be of non-childbearing potential, i.e. be abstinent, have a current tubal ligation, hysterectomy, ovariectomy or be post-menopausal or pre-menarcheal, or if she is of childbearing potential, she must use adequate contraception for 30 days prior to vaccination and continue for 2 months after completion of the vaccination series.

Exclusion Criteria:

- Previous vaccination against HPV or Hepatitis B virus.
- History of allergic disease or reactions likely to be exacerbated by any component of the vaccines.
- Acute disease at the time of enrolment. (Acute disease is defined as the presence of a moderate or severe illness with or without fever. All vaccines can be administered to persons with a minor illness such as diarrhoea, mild upper respiratory infection with or without low-grade febrile illness, i.e. Oral temperature <37.5°C (99.5°F) / Axillary temperature <37.5°C (99.5°F) / Rectal temperature <38°C (100.4°F).)
- Pregnant or lactating female.

Ages Eligible for Study

12 Years to 15 Years (Child)

Sexes Eligible for Study

All

Accepts Healthy Volunteers

Yes

Study Plan

This section provides details of the study plan, including how the study is designed and what the study is measuring.

How is the study designed?

Design Details

Primary Purpose : Prevention
Allocation : Randomized
Interventional Model : Parallel Assignment
Masking : None (Open Label)

Arms and Interventions

Participant Group/Arm	Intervention/Treatment
Experimental: Cervarix/Engerix-B A Group The A group includes subjects from communities where 70% of male and female adolescents were to be vaccinated with Cervarix vaccine. To achieve a Cervarix vaccination coverage of 70%, a 9:1 ratio was used to allocate study participants to receive Cervarix vaccine versus control Engerix-B vaccine (meaning 90% of vaccinated subjects were randomized to Cervarix). Finally, subjects from A group were either vaccinated with Cervarix, Engerix-B (control vaccine), or not vaccinated (enrolled control without vaccination). Vaccines were administered intramuscularly in the deltoid region of the non-dominant arm according to a 0, 1, 6-month schedule.	Biological: Cervarix • Intramuscular injection, 3 doses Biological: Engerix-B • Intramuscular injection, 3 doses

Experimental: Cervarix/Engerix-B B Group The B group includes subjects from communities where 70% of female adolescents were to be vaccinated with Cervarix vaccine. To achieve a Cervarix vaccination coverage of 70%, a 9:1 ratio was used to allocate female participants to receive Cervarix vaccine versus control Engerix-B vaccine (meaning 90% of vaccinated females were randomized to Cervarix). In this group, all male adolescents were to be vaccinated with Engerix-B control vaccine. Finally, subjects from B group were either vaccinated with Cervarix (females) or Engerix-B/not vaccinated (males and females). Vaccines were administered intramuscularly in the deltoid region of the non-dominant arm according to a 0, 1, 6-month schedule.	Biological: Cervarix • Intramuscular injection, 3 doses Biological: Engerix-B • Intramuscular injection, 3 doses

Active Comparator: Engerix-B Group In this control group, all adolescents were to be vaccinated with Engerix-B control vaccine. Finally, subjects from this group were either vaccinated with Engerix-B or not vaccinated. The vaccine was administered intramuscularly in the deltoid region of the non-dominant arm according to a 0, 1, 6-month schedule.	Biological: Engerix-B • Intramuscular injection, 3 doses

What is the study measuring?

Primary Outcome Measures

Outcome Measure	Measure Description	Time Frame
Number of Female Subjects With Overall Vaccine Effectiveness Against Genital Infection With Human Papilloma Virus (HPV)-16/18 Types in	The analysis of overall effectiveness of Cervarix vaccine against genital infection with HPV-16/18 types was based on stratified Mantel-Haenszel adjusted for clustering. The overall vaccine effectiveness was computed as 1- the prevalence odd ratio in all subjects from the investigated group (prevalence rate in all subjects from the investigated group/prevalence rate in all subjects from Engerix-B Group).	At the time of Visit 5 (i.e. at 18.5 years of age)

Cervarix/Engerix-B B Group Versus Engerix-B Group and in Cervarix/Engerix-B A Group Versus Engerix-B Group		

Secondary Outcome Measures

Outcome Measure	Measure Description	Time Frame
Number of Female Subjects With Overall Vaccine Effectiveness Against Genital Infection With HPV-16/18 Types in Cervarix/Engerix-B A Group Versus Cervarix/Engerix-B B Group	The analysis of overall effectiveness of Cervarix vaccine against genital infection with HPV-16/18 types was based on stratified Mantel-Haenszel adjusted for clustering. The overall vaccine effectiveness was computed as 1- the prevalence odd ratio in all subjects from the investigated group (prevalence rate in all subjects from the Cervarix/Engerix-B A Group/prevalence rate in all subjects from Engerix-B Group). Note: As per Protocol and as the confirmatory objectives were not met, only exploratory interpretation could be performed for what concerns this secondary outcome measure.	At the time of Visit 5 (i.e. at 18.5 years of age)
Number of Female Subjects With Overall Vaccine Effectiveness Against Genital Oncogenic Infection With	The analysis of overall effectiveness of Cervarix vaccine against genital infection with specific HPV types (16, 18, 31/45, 31/33/45, 31/33/45/51, 31/33/45/51/52, 31/33/35/39/45/51/52/56/58/59/66/68, 16/18/31/33/35/39/45/51/52/56/58/59/66/68, 6, 11, 6/11, 6/11/53/74) was based on stratified Mantel-Haenszel adjusted for clustering. The effectiveness was computed	At the time of Visit 5 (i.e. at 18.5 years of age)

Specific HPV Types	as 1- the prevalence odd ratio in all subjects from the investigated group (prevalence rate in all subjects from the investigated group/prevalence rate in all subjects from Engerix-B Group).	
Number of Female Subjects With Total Vaccine Effectiveness Against Oropharyngeal Infection With HPV-16/18 Types	The analysis of total effectiveness of Cervarix vaccine against oropharyngeal infection with HPV-16/18 types was based on stratified Mantel-Haenszel adjusted for clustering. The effectiveness was computed as 1- the prevalence odd ratio in Cervarix vaccinated subjects from the investigated group (prevalence rate in Cervarix vaccinated subjects from the investigated group/prevalence rate in all subjects from Engerix-B Group).	At the time of Visit 5 (i.e. at 18.5 years of age)
Number of Female Subjects With Total Vaccine Effectiveness Against Oropharyngeal Oncogenic Infection With Specific HPV Types	The analysis of total effectiveness of Cervarix vaccine against oropharyngeal infection with specific HPV types (16, 18, 31/45, 31/33/45, 31/33/45/51, 31/33/45/51/52, 31/33/35/39/45/51/52/56/58/59/66/68, 16/18/31/33/35/39/45/51/52/56/58/59/66/68, 6, 11, 6/11, 6/11/53/74) was based on stratified Mantel-Haenszel adjusted for clustering. The effectiveness was computed as 1- the prevalence odd ratio in all Cervarix vaccinated subjects from the investigated group (prevalence rate in all Cervarix vaccinated subjects from the investigated group/prevalence rate in all subjects from Engerix-B Group).	At the time of Visit 5 (at 18.5 years of age)
Number of Male Subjects Reporting Any and Grade 3 Solicited Local Symptoms, in a	Assessed solicited local symptoms were pain, redness and swelling. Any = occurrence of the symptom regardless of intensity grade. Grade 3 pain = pain that prevented normal activity. Grade 3 redness/swelling = redness/swelling	During the 7-day post-vaccination

Subset of Subjects	spreading beyond 50 millimeters (mm) of injection site.	period following each dose and across doses
Number of Male Subjects Reporting Any, Grade 3 and Related to Vaccination Solicited General Symptoms, in a Subset of Subjects	Assessed solicited general symptoms were arthralgia, fatigue, fever [defined as axillary temperature equal to or above 37.5 degrees Celsius (°C)], gastrointestinal symptoms (including nausea, vomiting, diarrhoea and/or abdominal pain), headache, myalgia, rash and urticaria. Any = occurrence of the symptom regardless of intensity grade. Grade 3 symptom = symptom that prevented normal activity. Grade 3 fever = fever > 39.0 °C. Related = symptom assessed by the investigator as related to the vaccination.	During the 7-day post-vaccination period following each dose and across doses
Number of Male Subjects Reporting Any, Grade 3 and Related to Vaccination Unsolicited Adverse Events (AEs), in a Subset of Subjects	An unsolicited AE covers any untoward medical occurrence in a clinical investigation subject temporally associated with the use of a medicinal product, whether or not considered related to the medicinal product and reported in addition to those solicited during the clinical study and any solicited symptom with onset outside the specified period of follow-up for solicited symptoms. Any was defined as the occurrence of any unsolicited AE regardless of intensity grade or relation to vaccination. Grade 3 AE = an AE which prevented normal, everyday activities. Related = AE assessed by the investigator as related to the vaccination.	Within the 30-day post-vaccination period
Number of Male Subjects	The number of subjects with urticaria/rash assessed within 30 minutes following each	Within 30

With Urticaria/Rash Within 30 Minutes After Each Vaccination Dose, in a Subset of Subjects	vaccine dose are reported. Confirmed urticaria/rash = subjects who reported urticaria/rash within the specified time frame. Not confirmed urticaria/rash = number of subjects who did not report urticaria/rash within the specified time frame.	minutes following each vaccination dose
Number of Male Subjects Reporting Medically Significant Conditions (MSCs), in a Subset of Subjects	MSCs are defined as AEs prompting emergency room or physician visits that are not (1) related to common diseases or (2) routine visits for physical examination or vaccination, or SAEs that are not related to common diseases. Common diseases include: upper respiratory infections, sinusitis, pharyngitis, gastroenteritis, urinary tract infections and injury.	From Dose 1 (at Day 0) until Month 12
Number of Male Subjects Reporting Any Serious Adverse Events (SAEs) and SAEs Causally Related to Vaccination, in a Subset of Subjects	Serious adverse events (SAEs) assessed include medical occurrences that resulted in death, were life-threatening, required hospitalization or prolongation of hospitalization or resulted in disability/incapacity.	From Dose 1 (at Day 0) until Month 12
Number of Subjects Reporting SAEs Assessed by the Investigator as Possibly	Serious adverse events (SAEs) assessed include medical occurrences that resulted in death, were life-threatening, required hospitalization or prolongation of hospitalization or resulted in disability/incapacity.	During the entire study period (from Day 0 up to

Related to Vaccination		Visit 5 [18.5 years of age] or up to the day before 19 years of age for subjects who did not attend Visit 5)

Number of Subjects With New Onset of Autoimmune Diseases (NOADs), Retrieved From Care Register for Social Welfare and Health Care (HILMO)	NOADs include colitis ulcerative, juvenile arthritis, type 1 diabetes mellitus, coeliac disease and Chron's disease, Basedow's disease, erythema nodosum VIIth nerve paralysis and psoriasis.	During the entire study period (from day 0 up to Visit 5 [at 18.5 years of age] or up to the day before 19 years of age for subjects who did not attend Visit 5)
Number of Subjects Reporting Pregnancies and Outcomes of Reported Pregnancies With Onset During the Study Period, Retrieved From Medical Birth Registry and HILMO	Pregnancies with onset during the study were classified by their outcome. Outcomes included live infant with no apparent congenital anomaly, elective termination with no apparent congenital anomaly, spontaneous abortion with no apparent congenital anomaly, ectopic pregnancy, stillbirth with no apparent congenital anomaly and molar pregnancy. Note: The analysis was performed based on the corrected demographical data. Please refer to the rationale provided in the Baseline characteristics section.	During the entire study period (from Day 0 up to Visit 5 [at 18.5 years of age] or up to the day before

		19 years of age for subjects who did not attend Visit 5)
Number of Subjects With HPV-16 and HPV-18 Antibody Concentrations Equal to or Above the Cut-off Values, by Gender, in a Subset of Subjects	The antibody concentrations against HPV-16 and HPV-18 were determined by Enzyme-linked immunosorbent assay (ELISA). The cut-off of the assay was 8 ELISA units per milliliter (EL.U/mL) for anti-HPV-16 and 7 EL.U/mL for anti-HPV-18 at Visits 1 and 4 and 19 EL.U/mL for HPV-16 and 18 EL.U/mL for HPV-18 at Visit 5.	At the time of Visit 1 (at Day 0), Visit 4 (at Month 7) and Visit 5 (at 18.5 years of age)
Anti-HPV-16 and Anti-HPV-18 Antibody Concentrations, by Gender, in a Subset of Subjects	The antibody concentrations against HPV-16 and HPV-18 were determined by Enzyme-linked immunosorbent assay (ELISA). The cut-off of the assay was 8 ELISA units per milliliter (EL.U/mL) for anti-HPV-16 and 7 EL.U/mL for anti-HPV-18 at Visits 1 and 4 and 19 EL.U/mL for HPV-16 and 18 EL.U/mL for HPV-18 at Visit 5.	At the time of Visit 1 (Day 0), Visit 4 (at Month 7) and at the time of Visit 5 (18.5 years of age)

Collaborators and Investigators

This is where you will find people and organizations involved with this study.

Sponsor

GlaxoSmithKline

Investigators

- Study Director: GSK Clinical Trials, GlaxoSmithKline

Publications

General

These publications are provided voluntarily by the person who enters information about the study and may be about anything related to the study.

- Lehtinen M, Eriksson T, Apter D, Hokkanen M, Natunen K, Paavonen J, Pukkala E, Angelo MG, Zima J, David MP, Datta S, Bi D, Struyf F, Dubin G. Safety of the human papillomavirus (HPV)-16/18 AS04-adjuvanted vaccine in adolescents aged 12-15 years: Interim analysis of a large community-randomized controlled trial. Hum Vaccin Immunother. 2016 Dec;12(12):3177-3185. doi: 10.1080/21645515.2016.1183847. (https://pubmed.ncbi.nlm.nih.gov/27841725)

From PubMed

These publications are automatically filled in from PubMed, a public database of scientific and medical articles, and may or may not be about the study.

- Bergman H, Henschke N, Arevalo-Rodriguez I, Buckley BS, Crosbie EJ, Davies JC, Dwan K, Golder SP, Loke YK, Probyn K, Petkovic J, Villanueva G, Morrison J. Human papillomavirus (HPV) vaccination for the prevention of cervical cancer and other HPV-related diseases: a network meta-analysis. Cochrane Database Syst Rev. 2025 Nov 24;11(11):CD015364. doi: 10.1002/14651858.CD015364.pub2. (https://pubmed.ncbi.nlm.nih.gov/41276263)

- Adhikari I, Eriksson T, Harjula K, Hokkanen M, Apter D, Nieminen P, Luostarinen T, Lehtinen M. Association of Chlamydia trachomatis infection with cervical atypia in adolescent women with short-term or long-term use of oral contraceptives: a longitudinal study in HPV vaccinated women. BMJ Open. 2022 Jun 1;12(6):e056824. doi: 10.1136/bmjopen-2021-056824. (https://pubmed.ncbi.nlm.nih.gov/35649600)

- Gray P, Kann H, Pimenoff VN, Eriksson T, Luostarinen T, Vanska S, Surcel HM, Faust H, Dillner J, Lehtinen M. Human papillomavirus seroprevalence in pregnant women following gender-neutral and girls-only vaccination programs in Finland: A cross-sectional cohort analysis following a cluster randomized trial. PLoS Med. 2021 Jun 7;18(6):e1003588. doi:

10.1371/journal.pmed.1003588. eCollection 2021 Jun. (https://pubmed.ncbi.nlm.nih.gov/34097688)

- Kalliala I, Eriksson T, Aro K, Hokkanen M, Lehtinen M, Gissler M, Nieminen P. Preterm birth rate after bivalent HPV vaccination: Registry-based follow-up of a randomized clinical trial. Prev Med. 2021 May;146:106473. doi: 10.1016/j.ypmed.2021.106473. Epub 2021 Feb 24. (https://pubmed.ncbi.nlm.nih.gov/33639181)

- Gray P, Kann H, Pimenoff VN, Adhikari I, Eriksson T, Surcel HM, Vanska S, Dillner J, Faust H, Lehtinen M. Long-term follow-up of human papillomavirus type replacement among young pregnant Finnish females before and after a community-randomised HPV vaccination trial with moderate coverage. Int J Cancer. 2020 Dec 15;147(12):3511-3522. doi: 10.1002/ijc.33169. Epub 2020 Jul 7. (https://pubmed.ncbi.nlm.nih.gov/32574384)

- Vanska S, Luostarinen T, Baussano I, Apter D, Eriksson T, Natunen K, Nieminen P, Paavonen J, Pimenoff VN, Pukkala E, Soderlund-Strand A, Dubin G, Garnett G, Dillner J, Lehtinen M. Vaccination With Moderate Coverage Eradicates Oncogenic Human Papillomaviruses If a Gender-Neutral Strategy Is Applied. J Infect Dis. 2020 Aug 17;222(6):948-956. doi: 10.1093/infdis/jiaa099. (https://pubmed.ncbi.nlm.nih.gov/32161969)

- Bi D, Apter D, Eriksson T, Hokkanen M, Zima J, Damaso S, Soila M, Dubin G, Lehtinen M, Struyf F. Safety of the AS04-adjuvanted human papillomavirus (HPV)-16/18 vaccine in adolescents aged 12-15 years: end-of-study results from a community-randomized study up to 6.5 years. Hum Vaccin Immunother. 2020 Jun 2;16(6):1392-1403. doi: 10.1080/21645515.2019.1692557. Epub 2019 Dec 12. (https://pubmed.ncbi.nlm.nih.gov/31829767)

- Lehtinen M, Apter D, Eriksson T, Harjula K, Hokkanen M, Lehtinen T, Natunen K, Damaso S, Soila M, Bi D, Struyf F. Effectiveness of the AS04-adjuvanted HPV-16/18 vaccine in reducing oropharyngeal HPV infections in young females-Results from a community-randomized trial. Int J Cancer. 2020 Jul 1;147(1):170-174. doi: 10.1002/ijc.32791. Epub 2019 Dec 14. (https://pubmed.ncbi.nlm.nih.gov/31736068)

- Lehtinen M, Luostarinen T, Vanska S, Soderlund-Strand A, Eriksson T, Natunen K, Apter D, Baussano I, Harjula K, Hokkanen M, Kuortti M, Palmroth J, Petaja T, Pukkala E, Rekonen S, Siitari-Mattila M, Surcel HM, Tuomivaara L, Paavonen J, Nieminen P, Dillner J, Dubin G, Garnett G. Gender-neutral vaccination provides improved control of human papillomavirus types 18/31/33/35 through herd immunity: Results of a community randomized trial (III). Int J Cancer. 2018 Nov 1;143(9):2299-2310. doi: 10.1002/ijc.31618. Epub 2018 Aug 10. (https://pubmed.ncbi.nlm.nih.gov/29845626)

- Lehtinen M, Soderlund-Strand A, Vanska S, Luostarinen T, Eriksson T, Natunen K, Apter D, Baussano I, Harjula K, Hokkanen M, Kuortti M, Palmroth J, Petaja T, Pukkala E, Rekonen S, Siitari-Mattila M, Surcel HM, Tuomivaara L, Paavonen J, Dillner J, Dubin G, Garnett G. Impact of gender-neutral or girls-only vaccination against human papillomavirus-Results of a community-randomized clinical trial (I). Int J Cancer. 2018 Mar 1;142(5):949-958. doi: 10.1002/ijc.31119. Epub 2017 Nov 9. (https://pubmed.ncbi.nlm.nih.gov/29055031)

- Lehtinen M, Apter D, Baussano I, Eriksson T, Natunen K, Paavonen J, Vanska S, Bi D, David MP, Datta S, Struyf F, Jenkins D, Pukkala E, Garnett G, Dubin G. Characteristics of a cluster-randomized phase IV human papillomavirus vaccination effectiveness trial. Vaccine. 2015 Mar 3;33(10):1284-90. doi: 10.1016/j.vaccine.2014.12.019. Epub 2015 Jan 12. (https://pubmed.ncbi.nlm.nih.gov/25593103)

Study Record Dates

These dates track the progress of study record and summary results submissions to ClinicalTrials.gov. Study records and reported results are reviewed by the National Library of Medicine (NLM) to make sure they meet specific quality control standards before being posted on the public website.

Study Registration Dates

First Submitted
2007-09-24

First Submitted that Met QC Criteria
2007-09-24

First Posted (Estimated)
2007-09-26

Results Reporting Dates

Results First Submitted
2015-12-17

Results First Submitted that Met QC Criteria
2015-12-17

Results First Posted (Estimated)
2016-01-26

Study Record Updates

Last Update Submitted that Met QC Criteria
2019-10-30

Last Update Posted
2019-11-15

Last Verified
2019-10

More Information

Terms related to this study

Keywords Provided by GlaxoSmithKline

HPV vaccine
Healthy adolescents
Cervical cancer
Safety
Immunogenicity
Cervarix

Additional Relevant MeSH Terms

Sexually Transmitted Diseases, Viral
Sexually Transmitted Diseases
Communicable Diseases
Infections
DNA Virus Infections
Virus Diseases
Tumor Virus Infections
Genital Diseases
Urogenital Diseases
Disease Attributes
Pathologic Processes
Pathological Conditions, Signs and Symptoms
Uterine Neoplasms
Genital Neoplasms, Female
Urogenital Neoplasms
Neoplasms by Site
Neoplasms
Uterine Cervical Diseases
Uterine Diseases
Genital Diseases, Female
Female Urogenital Diseases
Female Urogenital Diseases and Pregnancy Complications
Papillomavirus Infections
Uterine Cervical Neoplasms
human papillomavirus vaccine, L1 type 16, 18
Engerix-B

Plan for Individual Participant Data (IPD)

Plan to Share Individual Participant Data (IPD)?

Yes

IPD Plan Description

IPD is available via the Clinical Study Data Request site (click on the link provided below).

IPD Sharing Access Criteria

Access is provided after a research proposal is submitted and has received approval from the Independent Review Panel and after a Data Sharing Agreement is in place. Access is provided for an initial period of 12 months but an extension can be granted, when justified, for up to another 12 months.

IPD Sharing Time Frame

IPD is available via the Clinical Study Data Request site (click on the link provided below).

IPD Sharing Supporting Information Type

Study Protocol
Statistical Analysis Plan (SAP)
Informed Consent Form (ICF)
Clinical Study Report (CSR)

IPD Sharing Url

https://www.clinicalstudydatarequest.com/Posting.aspx?ID=4582 (https://www.clinicalstudydatarequest.com/Posting.aspx?ID=4582)

Study Information

1. Individual Participant Data Set (https://www.clinicalstudydatarequest.com)

   Information Identifier

   106636

   Information Comments

   For additional information about this study please refer to the GSK Clinical Study Register

2. Statistical Analysis Plan (https://www.clinicalstudydatarequest.com)

   Information Identifier

   106636

   Information Comments

   For additional information about this study please refer to the GSK Clinical Study Register

3. Clinical Study Report (https://www.clinicalstudydatarequest.com)

   Information Identifier

106636

Information Comments

For additional information about this study please refer to the GSK Clinical Study Register

4. Dataset Specification (https://www.clinicalstudydatarequest.com)

Information Identifier

106636

Information Comments

For additional information about this study please refer to the GSK Clinical Study Register

5. Informed Consent Form (https://www.clinicalstudydatarequest.com)

Information Identifier

106636

Information Comments

For additional information about this study please refer to the GSK Clinical Study Register

6. Study Protocol (https://www.clinicalstudydatarequest.com)

Information Identifier

106636

Information Comments

For additional information about this study please refer to the GSK Clinical Study Register

7. Annotated Case Report Form (https://www.clinicalstudydatarequest.com)

Information Identifier

106636

Information Comments

For additional information about this study please refer to the GSK Clinical Study Register

Drug and device information, study documents, and helpful links

Helpful Links Provided by GlaxoSmithKline

Researchers can use this site to request access to anonymised patient level data and/or supporting documents from clinical studies to conduct further research.
(https://www.clinicalstudydatarequest.com)