ISRCTN90378590 https://doi.org/10.1186/ISRCTN90378590

Epidemiological studies on human papillomavirus (HPV)

Submission date
24/11/2008

Recruitment status
No longer recruiting

Registration date
30/01/2009

Overall study status
Completed

Last Edited
30/01/2009

Condition category
Infections and Infestations

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Deborah Watson-Jones

Contact details
London School of Hygiene & Tropical Medicine
Keppel Street
London
United Kingdom
WC1E 7HT
+44 (0)20 7927 2116
deborah.watson-jones@lshtm.ac.uk

Additional identifiers

Study information

Scientific Title

Study objectives
These epidemiological studies are nested within a Phase IIIB trial examining the immunogenicity and safety of GSK's bivalent vaccine in Mwanza, Tanzania (ClinicalTrials.gov identifier NCT00481767). The objectives of the studies are to:

1. Measure the prevalence and incidence of genital human papillomavirus (HPV) infection and the prevalence of cervical pathology in the HPV vaccine cohort and risk factors for HPV infection
2. Measure HIV prevalence (at screening) and incidence (at 12 months) and risk factors for infection in cohort at screening
3. Measure prevalence of sexually transmitted infections (STIs) and risk factors for infection
4. Determine whether the presence and/or burden of parasitic infections influence the vaccine response
5. Determine whether prior HPV infection (in particular with types targeted by the vaccine) modifies the response to vaccination

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Ethics Committee of the London School of Hygiene & Tropical Medicine (LSHTM) (UK), approved on 05/06/2008 (ref: 5305)
2. Medical Research Coordinating Committee of the National Institute for Medical Research (Tanzania), approved on 20/05/2008

Study design
Supplementary epidemiological studies nested within a double-blind randomised placebo-controlled phase IIIB trial

Primary study design
Observational

Study type(s)
Other

Health condition(s) or problem(s) studied
Human papillomavirus (HPV)

Interventions
The intervention is GSK Biologicals' candidate HPV vaccine containing HPV-16/18 L1 proteins and AS04 adjuvant administered intramuscularly using a three-dose schedule (0, 1, 6 months).

The placebo control injection, given using the same dose schedule, contains 500 µg of aluminium as Al(OH)3.

Intervention Type
Drug

Phase
Phase III

Drug/device/biological/vaccine name(s)
Human papillomavirus (HPV) vaccine (GSK serial number: 580299)

Primary outcome(s)
1. Prevalence at enrolment and incidence of genital HPV infection at Month 12
2. Prevalence of cervical pathology at enrolment

3. Influence of presence and/or burden of parasitic infection on vaccine response at Month 7
4. Effect of prior HPV infection (in particular with types targeted by the vaccine) on the response to HPV vaccine at Month 12

Key secondary outcome(s)
1. HIV and STI prevalence and incidence
2. Risk factors for HIV and STI

Assessment schedule:

Screening (day -30):
a. Sero-prevalence of HIV and risk factors for HIV
b. Sero-prevalence of HPV and risk factors for HPV

Enrolment (day 0):
Prevalence of and risk factors for genital HPV infection and other reproductive tract infections

Month 12:
Incident HIV and incident genital HPV infection

Completion date
30/05/2010

Eligibility

Key inclusion criteria
1. Female subjects aged 10-25 years
2. Subjects who the investigator believes that they and/or their parents/legally acceptable representative can and will comply with the requirements of the protocol should be enrolled in the study
3. A female between, and including, 10 and 25 years of age at the time of the first vaccination
4. Written or oral, signed or thumb printed or witnessed informed consent obtained from the subject prior to enrolment for both the main GSK vaccine trial and for the epidemiological studies on HPV. For subjects below legal age of consent, written or oral, signed or thumb printed or witnessed informed consent obtained from the subject's parent or legally acceptable representative.
5. Free of obvious health problems as established by medical history, clinical examination and laboratory testing before entering into the study.
6. Subjects must have a negative urine pregnancy test at the screening visit and at Visit 1 (Day 0)
7. Subjects must be seronegative for human immunodeficiency virus (HIV) at the screening visit
8. Subjects must be of non-childbearing potential, or, if of childbearing potential, she must be abstinent or have used adequate contraceptive precautions for 30 days prior to vaccination, have a negative pregnancy test and must agree to continue such precautions for two months after completion of the vaccination series. Subjects who reach menarche during the study and therefore are of childbearing potential must agree to follow the same precautions.
9. Subjects must have had no more than 6 sexual partners prior to enrolment
10. Subjects must be willing to undergo HIV voluntary counselling and testing and must be willing to be informed of their HIV status. Subjects below legal age of consent must also be willing to have their parent or legally acceptable representative informed of their HIV status.

Participant type(s)

Patient

Healthy volunteers allowed
No

Age group
Other

Sex
Female

Key exclusion criteria
1. Use of any investigational or non-registered product (drug or vaccine) other than the study vaccines within 30 days preceding the first dose of study vaccine, or planned use during the study period (up to Month 12)
2. Chronic administration of immunosuppressants or other immune-modifying drugs within six months prior to the first vaccine dose or planned administration during the study period
3. Administration of a vaccine not foreseen by the study protocol within 30 days before the first dose of vaccine. Enrolment will be deferred until the subject is outside of specified window.
4. Planned administration of a vaccine not foreseen by the study protocol within 30 days before and 30 days after any dose of study vaccine
5. Previous vaccination against HPV, or planned administration of any HPV vaccine other than that foreseen by the study protocol during the study period
6. Previous administration of components of the investigational vaccine
7. Cancer or autoimmune disease under treatment
8. Any confirmed or suspected immunosuppressive or immunodeficient condition, including HIV infection based on laboratory testing performed during the screening visit
9. Hypersensitivity to latex
10. History of allergic disease or reactions likely to be exacerbated by any component of the vaccine/control
11. Acute disease at the time of enrolment
12. Acute or chronic, clinically significant pulmonary, cardiovascular, hepatic or renal functional abnormality, as determined by physical examination or laboratory testing performed at the screening visit
13. History of any neurologic disorders or seizures
14. Administration of immunoglobulins and/or any blood products within the three months preceding the first dose of study vaccine or planned administration during the study period
15. Pregnant or breastfeeding female
16. A women planning to become pregnant, likely to become pregnant or planning to discontinue contraceptive precautions during the study period, up to two months after the last vaccine dose
17. Concurrently participating in another clinical study, at any time during the study period, in which the subject has been or will be exposed to an investigational or a non-investigational product (pharmaceutical product or device)

Date of first enrolment
20/10/2008

Date of final enrolment
30/05/2010

Locations

Countries of recruitment
United Kingdom

England

Tanzania

Study participating centre
London School of Hygiene & Tropical Medicine
London
United Kingdom
WC1E 7HT

Sponsor information

Organisation
London School of Hygiene & Tropical Medicine (UK)

ROR
https://ror.org/00a0jsq62

Funder(s)

Funder type
Industry

Funder Name
GSK Biologicals (Belgium)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration