Clinical trial results:
Estudio ginecológico de extensión, fase IIIb, abierto y multicéntrico, para el seguimiento de un subgrupo de sujetos del estudio 580299/008 que presentaron, en la última visita del estudio (visita 10, mes 48), una citología cervical negativa pero eran positivas para HPV oncogénicos, o que se encontraban embarazadas en la última visita del estudio 580299/008

Summary

EudraCT number	2008-008124-33
Trial protocol	FI ES DE GB
Global end of trial date	20 January 2014

Results information

Result version number	v1
This version publication date	27 April 2016
First version publication date	24 January 2015

Trial information

Trial identification

Sponsor protocol code	112024

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT00937950
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	GlaxoSmithKline Biologicals
Sponsor organisation address	Rue de l'Institut 89, Rixensart, Belgium, B-1330
Public contact	Clinical Trials Call Center, GlaxoSmithKline Biologicals, 044 2089-904466, GSKClinicalSupportHD@gsk.com
Scientific contact	Clinical Trials Call Center, GlaxoSmithKline Biologicals, 044 2089-904466, GSKClinicalSupportHD@gsk.com

Notes:

Paediatric regulatory details

Is trial part of an agreed paediatric investigation plan (PIP)	No
Does article 45 of REGULATION (EC) No 1901/2006 apply to this trial?	No
Does article 46 of REGULATION (EC) No 1901/2006 apply to this trial?	No

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	04 August 2014
Is this the analysis of the primary completion data?	Yes
Primary completion date	20 January 2014
Global end of trial reached?	Yes
Global end of trial date	20 January 2014
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

Proporcionar asistencia clínica y/o tratamiento a los sujetos que, al final del estudio HPV-008, mostraran una citología cervical normal pero un resultado positivo para infección por HPV oncogénicos o a las mujeres participantes que estuvieran embarazadas al final del estudio HPV-008 y a las que no hubiera podido recoger ninguna muestra cervical.
Notificar los AAG fatales, los AAG relacionados con la participación en el estudio y los AAG relacionados con medicación concomitante de GSK

Protection of trial subjects:

As with all injectable vaccines, appropriate medical treatment was always readily available in case of anaphylactic reactions following the administration of the vaccine. For this reason, the vaccine remained under medical supervision for 30 minutes after vaccination.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	05 August 2009
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	Yes

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Spain: 53
Country: Number of subjects enrolled	United Kingdom: 42
Country: Number of subjects enrolled	Finland: 764
Country: Number of subjects enrolled	Germany: 92
Country: Number of subjects enrolled	Australia: 49
Country: Number of subjects enrolled	Belgium: 13
Country: Number of subjects enrolled	Brazil: 211
Country: Number of subjects enrolled	Canada: 40
Country: Number of subjects enrolled	Italy: 1
Country: Number of subjects enrolled	Philippines: 308
Country: Number of subjects enrolled	Taiwan: 105
Country: Number of subjects enrolled	Thailand: 249
Country: Number of subjects enrolled	United States: 95
Worldwide total number of subjects	2022
EEA total number of subjects	965

Notes:

Subjects enrolled per age group	
In utero	0
Preterm newborn - gestational age < 37 wk	0
Newborns (0-27 days)	0
Infants and toddlers (28 days-23 months)	0
Children (2-11 years)	0
Adolescents (12-17 years)	0
Adults (18-64 years)	2022
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

During the screening the following steps occurred: check for inclusion/exclusion criteria, contraindications/precautions, medical history of the subjects and signing informed consent forms.

Pre-assignment period milestones

Number of subjects started	2022
Number of subjects completed	2003

Pre-assignment subject non-completion reasons

Reason: Number of subjects	Subjects not eligible: 19

Period 1

Period 1 title	Overall (overall period)
Is this the baseline period?	Yes
Allocation method	Not applicable
Blinding used	Not blinded

Arms

Arm title	Cervarix Arm

Arm description:

The study group consisted a subset of HPV-008 subjects who at their last study visit of study HPV-008 (Visit 10, Month 48) displayed normal cervical cytology but tested positive for oncogenic HPV infection or were pregnant so that no cervical sample could be collected at that visit. In the HPV-008 study, the subjects in this group had received 3 doses of Havrix™.

Arm type	Active comparator
Investigational medicinal product name	Havrix™
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

Intramuscular injection, 3 doses

Number of subjects in period 1[1]	Cervarix Arm
Started	2003
Completed	1787
Not completed	216
Consent withdrawn by subject	23
Others	18
Migrated/moved from study area	27

Lost to follow-up	144
Missing confirmed	4

Notes:

[1] - The number of subjects reported to be in the baseline period are not the same as the worldwide number enrolled in the trial. It is expected that these numbers will be the same.

Justification: Out of the 2022 subjects enrolled, 19 did not fulfill eligibility criteria and were excluded, hence 2003 subjects started the study.

Baseline characteristics

Reporting groups	
Reporting group title	Cervarix Arm

Reporting group description:

The study group consisted a subset of HPV-008 subjects who at their last study visit of study HPV-008 (Visit 10, Month 48) displayed normal cervical cytology but tested positive for oncogenic HPV infection or were pregnant so that no cervical sample could be collected at that visit. In the HPV-008 study, the subjects in this group had received 3 doses of Havrix™.

Reporting group values	Cervarix Arm	Total	
Number of subjects	2003	2003	
Age categorical Units: Subjects			
In utero		0	
Preterm newborn infants (gestational age < 37 wks)		0	
Newborns (0-27 days)		0	
Infants and toddlers (28 days-23 months)		0	
Children (2-11 years)		0	
Adolescents (12-17 years)		0	
Adults (18-64 years)		0	
From 65-84 years		0	
85 years and over		0	
Age continuous Units: years			
geometric mean	24.3		
standard deviation	± 3.06	-	
Gender categorical Units: Subjects			
Female	2003	2003	
Male	0	0	

End points

End points reporting groups

Reporting group title	Cervarix Arm

Reporting group description:

The study group consisted a subset of HPV-008 subjects who at their last study visit of study HPV-008 (Visit 10, Month 48) displayed normal cervical cytology but tested positive for oncogenic HPV infection or were pregnant so that no cervical sample could be collected at that visit. In the HPV-008 study, the subjects in this group had received 3 doses of Havrix™.

Primary: Number of subjects with HPV DNA in cervical samples by HCII

End point title	Number of subjects with HPV DNA in cervical samples by

End point description:

Subjects that presented oncogenic HPV DNA in cervical samples by HPV DNA testing (Hybrid Capture® 2 test [HCII]).

End point type	Primary

End point timeframe:

At Months 12, 24, 36, 48

Notes:

[1] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: The analysis of the primary endpoint was descriptive i.e. no statistical hypothesis test was performed.

End point values	Cervarix Arm			
Subject group type	Reporting group			
Number of subjects analysed	1467			
Units: Subjects				
Positive DNA (Month 12 Post HPV-008)	615			
Positive DNA (Month 24 Post HPV-008)	418			
Positive DNA (Month 36 Post HPV-008)	255			
Positive DNA (Month 48 Post HPV-008)	144			
Negative DNA (Month 12 Post HPV-008)	828			
Negative DNA (Month 24 Post HPV-008)	444			
Negative DNA (Month 36 Post HPV-008)	236			
Negative DNA (Month 48 Post HPV-008)	107			

Statistical analyses

No statistical analyses for this end point

Primary: Number of subjects with colposcopy referral and colposcopy adequacy

End point title	Number of subjects with colposcopy referral and colposcopy adequacy[2]

End point description:

Subjects with colposcopy referral and colposcopy adequacy.

End point type	Primary

End point timeframe:

At Months 12, 24, 36, 48

Notes:

[2] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: The analysis of the primary endpoint was descriptive i.e. no statistical hypothesis test was performed.

End point values	Cervarix Arm			
Subject group type	Reporting group			
Number of subjects analysed	2003			
Units: Subjects				
Colposcopy referral (Month 12) Yes	572			
Colposcopy referral (Month 12) No	1429			
Colposcopy referral (Month 12) Missing	2			
Algorithm respected (Month 12) Yes	371			
Algorithm respected (Month 12) No	21			
Colposcopy adequacy (Month 12), Satisfactory	370			
Colposcopy adequacy (Month 12), Unsatisfactory	18			
Colposcopy adequacy (Month 12), Missing	4			
Colposcopy referral (Month 24) Yes	385			
Colposcopy referral (Month 24) No	1615			
Colposcopy referral (Month 24) Missing	3			
Algorithm respected (Month 24) Yes	254			
Algorithm respected (Month 24) No	8			
Algorithm respected (Month 24) Missing	1			
Colposcopy adequacy (Month 24), Satisfactory	245			
Colposcopy adequacy (Month 24), Unsatisfactory	14			
Colposcopy adequacy (Month 24), Missing	4			
Colposcopy referral (Month 36) Yes	224			
Colposcopy referral (Month 36) No	1776			
Colposcopy referral (Month 36) Missing	3			
Algorithm respected (Month 36) Yes	154			
Algorithm respected (Month 36) No	4			
Colposcopy adequacy (Month 36), Satisfactory	150			
Colposcopy adequacy (Month 36), Unsatisfactory	7			
Colposcopy adequacy (Month 36), Missing	1			
Colposcopy referral (Month 48) Yes	133			
Colposcopy referral (Month 48) No	1867			
Colposcopy referral (Month 48) Missing	3			
Algorithm respected (Month 48) Yes	96			
Algorithm respected (Month 48) No	0			
Colposcopy adequacy (Month 48), Satisfactory	92			
Colposcopy adequacy (Month 48), Unsatisfactory	3			

Colposcopy adequacy (Month 48), Missing	1			

Statistical analyses

No statistical analyses for this end point

Primary: Number of subjects with cervical cytology

End point title	Number of subjects with cervical cytology[3]

End point description:

Subjects who presented normal, ASC-US (Atypical Squamous Cell of Undetermined Significance), LSIL (Low-grade Squamous Intraepithelial Lesions), HSIL (High-grade Squamous Intraepithelial Lesions), AGC (Atypical Glandular Cells), ASC-H (Atypical Squamous Cells cannot exclude HSIL) cervical cytology.

End point type	Primary

End point timeframe:

At Months 12, 24, 36, 48

Notes:

[3] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: The analysis of the primary endpoint was descriptive i.e. no statistical hypothesis test was performed.

End point values	Cervarix Arm			
Subject group type	Reporting group			
Number of subjects analysed	1467			
Units: Subjects				
Normal, Month 12 (N=1467)	1193			
ASC-US, Month 12 (N=1467)	154			
ASC-H, Month 12 (N=1467)	8			
LSIL, Month 12 (N=1467)	100			
HSIL, Month 12 (N=1467)	8			
AGC, Month 12 (N=1467)	4			
Normal, Month 24 (N=867)	662			
ASC-US, Month 24 (N=867)	117			
ASC-H, Month 24 (N=867)	11			
LSIL, Month 24 (N=867)	68			
HSIL, Month 24 (N=867)	7			
AGC, Month 24 (N=867)	2			
Normal, Month 36 (N=494)	390			
ASC-US, Month 36 (N=494)	58			
ASC-H, Month 36 (N=494)	4			
LSIL, Month 36 (N=494)	34			
HSIL, Month 36 (N=494)	5			
AGC, Month 36 (N=494)	3			
Normal, Month 48 (N=258)	206			
ASC-US, Month 48 (N=258)	28			
ASC-H, Month 48 (N=258)	0			
LSIL, Month 48 (N=258)	16			
HSIL, Month 48 (N=258)	6			

AGC, Month 48 (N=258)	2			

Statistical analyses

No statistical analyses for this end point

Primary: Number of subjects with cervical biopsy results

End point title	Number of subjects with cervical biopsy results[4]

End point description:

Subjects with negative and positive cervical biopsy results for only CIN1, only CIN2, only CIN3, CIN1 and CIN2, CIN1 and CIN3, CIN2 and CIN3, CIN1 and CIN2 and CIN3, AIS, Invasive malignancy, other.

End point type	Primary

End point timeframe:

At Month 12

Notes:

[4] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: The analysis of the primary endpoint was descriptive i.e. no statistical hypothesis test was performed.

End point values	Cervarix Arm			
Subject group type	Reporting group			
Number of subjects analysed	199			
Units: Subjects				
Negative	76			
Only CIN1(positive)	41			
Only CIN1(negative)	158			
Only CIN2 (positive)	18			
Only CIN2 (negative)	181			
Only CIN3 (positive)	8			
Only CIN3 (negative)	191			
CIN1 and CIN2 (positive)	3			
CIN1 and CIN2(negative)	196			
CIN1 and CIN3(positive)	1			
CIN1 and CIN3 (negative)	198			
CIN2 and CIN3 (positive)	1			
CIN2 and CIN3 (negative)	198			
CIN1 and CIN2 and CIN3 (positive)	0			
CIN1 and CIN2 and CIN3 (negative)	199			
AIS (positive)	0			
AIS (negative)	199			
Invasive malignancy (positive)	0			
Invasive malignancy (negative)	199			
Other	85			

Statistical analyses

No statistical analyses for this end point

Primary: Number of subjects with cervical biopsy results

End point title	Number of subjects with cervical biopsy results[5]

End point description:

Subjects with negative and positive cervical biopsy results for only CIN1, only CIN2, only CIN3, CIN1 and CIN2, CIN1 and CIN3, CIN2 and CIN3, CIN1 and CIN2 and CIN3, AIS, Invasive malignancy, other.

End point type	Primary

End point timeframe:

At Month 24

Notes:

[5] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: The analysis of the primary endpoint was descriptive i.e. no statistical hypothesis test was performed.

End point values	Cervarix Arm			
Subject group type	Reporting group			
Number of subjects analysed	147			
Units: Subjects				
Negative	38			
Only CIN1(positive)	47			
Only CIN1(negative)	100			
Only CIN2 (positive)	8			
Only CIN2 (negative)	139			
Only CIN3 (positive)	8			
Only CIN3 (negative)	139			
CIN1 and CIN2 (positive)	2			
CIN1 and CIN2(negative)	145			
CIN1 and CIN3(positive)	0			
CIN1 and CIN3 (negative)	147			
CIN2 and CIN3 (positive)	1			
CIN2 and CIN3 (negative)	146			
CIN1 and CIN2 and CIN3 (positive)	0			
CIN1 and CIN2 and CIN3 (negative)	147			
AIS (positive)	1			
AIS (negative)	146			
Invasive malignancy (positive)	0			
Invasive malignancy (negative)	147			
Other	56			

Statistical analyses

No statistical analyses for this end point

Primary: Number of subjects with cervical biopsy results

End point title	Number of subjects with cervical biopsy results[6]

End point description:

Subjects with negative and positive cervical biopsy results for only CIN1, only CIN2, only CIN3, CIN1 and CIN2, CIN1 and CIN3, CIN2 and CIN3, CIN1 and CIN2 and CIN3, AIS, Invasive malignancy, other.

End point type	Primary

End point timeframe:

At Month 36

Notes:

[6] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: The analysis of the primary endpoint was descriptive i.e. no statistical hypothesis test was performed.

End point values	Cervarix Arm			
Subject group type	Reporting group			
Number of subjects analysed	88			
Units: Subjects				
Negative	31			
Only CIN1(positive)	31			
Only CIN1(negative)	57			
Only CIN2 (positive)	6			
Only CIN2 (negative)	82			
Only CIN3 (positive)	3			
Only CIN3 (negative)	85			
CIN1 and CIN2 (positive)	0			
CIN1 and CIN2(negative)	88			
CIN1 and CIN3(positive)	0			
CIN1 and CIN3 (negative)	88			
CIN2 and CIN3 (positive)	0			
CIN2 and CIN3 (negative)	88			
CIN1 and CIN2 and CIN3 (positive)	0			
CIN1 and CIN2 and CIN3 (negative)	88			
AIS (positive)	0			
AIS (negative)	88			
Invasive malignancy (positive)	0			
Invasive malignancy (negative)	88			
Other	25			

Statistical analyses

No statistical analyses for this end point

Primary: Number of subjects with cervical biopsy results

End point title	Number of subjects with cervical biopsy results[7]

End point description:

Subjects with negative and positive cervical biopsy results for only CIN1, only CIN2, only CIN3, CIN1 and CIN2, CIN1 and CIN3, CIN2 and CIN3, CIN1 and CIN2 and CIN3, AIS, Invasive malignancy, other.

End point type	Primary

End point timeframe:

At Month 48

Notes:

[7] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: The analysis of the primary endpoint was descriptive i.e. no statistical hypothesis test was performed.

End point values	Cervarix Arm			
Subject group type	Reporting group			
Number of subjects analysed	54			
Units: Subjects				
Negative	21			
Only CIN1(positive)	15			
Only CIN1(negative)	39			
Only CIN2 (positive)	5			
Only CIN2 (negative)	49			
Only CIN3 (positive)	2			
Only CIN3 (negative)	52			
CIN1 and CIN2 (positive)	1			
CIN1 and CIN2(negative)	53			
CIN1 and CIN3(positive)	0			
CIN1 and CIN3 (negative)	54			
CIN2 and CIN3 (positive)	0			
CIN2 and CIN3 (negative)	54			
CIN1 and CIN2 and CIN3 (positive)	0			
CIN1 and CIN2 and CIN3 (negative)	54			
AIS (positive)	0			
AIS (negative)	54			
Invasive malignancy (positive)	0			
Invasive malignancy (negative)	54			
Other	11			

Statistical analyses

No statistical analyses for this end point

Primary: Number of subjects with treatment referrals by treatment type

End point title	Number of subjects with treatment referrals by treatment

End point description:

Subjects who presented treatment referral, Loop excision of cervix, Loop cone of cervix, Cold knife cone of cervix, Laser excision, other.

End point type	Primary

End point timeframe:

At Month 12

Notes:

[8] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: The analysis of the primary endpoint was descriptive i.e. no statistical hypothesis test was performed.

End point values	Cervarix Arm			
Subject group type	Reporting group			
Number of subjects analysed	392			
Units: Subjects				
Treatment referral, Yes	33			
Treatment referral, No	359			
Loop excision of cervix, Yes	14			
Loop excision of cervix, No	18			
Loop cone of cervix, Yes	15			
Loop cone of cervix, No	17			
Cold knife cone of cervix, Yes	0			
Cold knife cone of cervix, No	32			
Laser excision, Yes	1			
Laser excision, No	31			
Other	4			

Statistical analyses

No statistical analyses for this end point

Primary: Number of subjects with treatment referrals by treatment type

End point title	Number of subjects with treatment referrals by treatment

End point description:

Subjects who presented treatment referral, Loop excision of cervix, Loop cone of cervix, Cold knife cone of cervix, Laser excision, other.

End point type	Primary

End point timeframe:

At Month 24

Notes:

[9] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: The analysis of the primary endpoint was descriptive i.e. no statistical hypothesis test was performed.

End point values	Cervarix Arm			
Subject group type	Reporting group			
Number of subjects analysed	263			
Units: Subjects				
Treatment referral, Yes	19			
Treatment referral, No	243			
Treatment referral, Missing	1			
Loop excision of cervix, Yes	9			
Loop excision of cervix, No	8			
Loop cone of cervix, Yes	4			
Loop cone of cervix, No	13			
Cold knife cone of cervix, Yes	1			
Cold knife cone of cervix, No	16			
Laser excision, Yes	0			
Laser excision, No	17			

Other	4			

Statistical analyses

No statistical analyses for this end point

Primary: Number of subjects with treatment referrals by treatment type

End point title	Number of subjects with treatment referrals by treatment

End point description:

Subjects who presented treatment referral, Loop excision of cervix, Loop cone of cervix, Cold knife cone of cervix, Laser excision, other.

End point type	Primary

End point timeframe:

At Month 36

Notes:

[10] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: The analysis of the primary endpoint was descriptive i.e. no statistical hypothesis test was performed.

End point values	Cervarix Arm			
Subject group type	Reporting group			
Number of subjects analysed	158			
Units: Subjects				
Treatment referral, Yes	13			
Treatment referral, No	145			
Loop excision of cervix, Yes	4			
Loop excision of cervix, No	6			
Loop cone of cervix, Yes	4			
Loop cone of cervix, No	6			
Cold knife cone of cervix, Yes	0			
Cold knife cone of cervix, No	10			
Laser excision, Yes	0			
Laser excision, No	10			
Other	2			

Statistical analyses

No statistical analyses for this end point

Primary: Number of subjects with treatment referrals by treatment type

End point title	Number of subjects with treatment referrals by treatment

End point description:

Subjects who presented treatment referral, Loop excision of cervix, Loop cone of cervix, Cold knife cone of cervix, Laser excision, other.

End point type	Primary

End point timeframe:

At Month 48

Notes:

[11] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: The analysis of the primary endpoint was descriptive i.e. no statistical hypothesis test was performed.

End point values	Cervarix Arm			
Subject group type	Reporting group			
Number of subjects analysed	96			
Units: Subjects				
Treatment referral, Yes	9			
Treatment referral, No	87			
Loop excision of cervix, Yes	1			
Loop excision of cervix, No	7			
Loop cone of cervix, Yes	5			
Loop cone of cervix, No	3			
Cold knife cone of cervix, Yes	0			
Cold knife cone of cervix, No	8			
Laser excision, Yes	1			
Laser excision, No	7			
Other	1			

Statistical analyses

No statistical analyses for this end point

Primary: Number of subjects with AEs or SAEs leading to withdrawal

End point title	Number of subjects with AEs or SAEs leading to withdrawal[12]

End point description:

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.

End point type	Primary

End point timeframe:

Up to Month 48

Notes:

[12] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: The analysis of the primary endpoint was descriptive i.e. no statistical hypothesis test was performed.

End point values	Cervarix Arm			
Subject group type	Reporting group			
Number of subjects analysed	2003			
Units: Subjects	216			

Statistical analyses

No statistical analyses for this end point

Primary: Number of subjects with any fatal SAEs, with any SAEs assessed as possibly related to study participation or to a concurrent GSK medication.

End point title	Number of subjects with any fatal SAEs, with any SAEs assessed as possibly related to study participation or to a concurrent GSK medication.[13]

End point description:

Serious adverse events (SAEs) assessed include medical occurrences that result in death, are life threatening, require hospitalization or prolongation of hospitalization or result in disability/incapacity.

End point type	Primary

End point timeframe:

Up to Month 48

Notes:

[13] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: The analysis of the primary endpoint was descriptive i.e. no statistical hypothesis test was performed.

End point values	Cervarix Arm			
Subject group type	Reporting group			
Number of subjects analysed	2003			
Units: Subjects				
Subjects with fatal SAEs	0			
Subjects with any related SAEs	0			
Subjects with any SAEs due to concurrent GSK medic	0			

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information[1]	
Timeframe for reporting adverse events:	
AEs and SAEs:From Day 0 to Month 48.	
Adverse event reporting additional description:	
Other Adverse Events were not assessed in this study.	
Assessment type	Non-systematic

Dictionary used	
Dictionary name	MedDRA
Dictionary version	17.0

Frequency threshold for reporting non-serious adverse events: 5 %

Notes:

[1] - There are no non-serious adverse events recorded for these results. It is expected that there will be at least one non-serious adverse event reported.
Justification: There were no non-serious adverse events reported.

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? No

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported