



Clinical trial results:

Follow-up study to evaluate the long-term immunogenicity and safety of a HPV vaccine (580299) in healthy female subjects

Summary

EudraCT number	2008-000369-44
Trial protocol	DE
Global end of trial date	06 January 2015

Results information

Result version number	v1 (current)
This version publication date	11 May 2016
First version publication date	19 June 2015

Trial information

Trial identification

Sponsor protocol code	111375
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Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT00877877
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?	Yes

Notes:

Results analysis stage

Analysis stage	Interim
Date of interim/final analysis	21 January 2015
Is this the analysis of the primary completion data?	Yes
Primary completion date	06 January 2015
Global end of trial reached?	Yes
Global end of trial date	06 January 2015
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To evaluate the long-term immunogenicity of the HPV-16/18 vaccine by enzyme-linked immunosorbent assay (ELISA).

Protection of trial subjects:

All subjects were supervised closely for at least 30 minutes following vaccination with appropriate medical treatment readily available. Vaccines were administered by qualified and trained personnel. Vaccines/products were administered only to eligible subjects that had no contraindications to any components of the vaccines. Subjects were followed-up from the time the subject consents to participate in the study until she/he is discharged.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	07 May 2008
Long term follow-up planned	Yes
Long term follow-up rationale	Safety
Long term follow-up duration	10 Years
Independent data monitoring committee (IDMC) involvement?	Yes

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Colombia: 96
Country: Number of subjects enrolled	Germany: 208
Country: Number of subjects enrolled	Panama: 123
Country: Number of subjects enrolled	Taiwan: 103
Country: Number of subjects enrolled	Honduras: 102
Worldwide total number of subjects	632
EEA total number of subjects	208

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	0

months)	
Children (2-11 years)	0
Adolescents (12-17 years)	632
Adults (18-64 years)	0
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

Subjects who participated in the primary study (NCT00196924) and received 3 doses of Cervarix.

Pre-assignment

Screening details:

Subjects enrolled in this study were primed with Cervarix vaccine as part of study NCT00196924. Subjects not returning for a specific visit were not withdrawn and could participate in the subsequent follow-up phases. Actual enrollment differed depending on the rate of return for the follow-up study, so not all subjects enrolled came to each visit.

Period 1

Period 1 title	Month 60
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Not blinded

Arms

Arm title	Cervarix Month 60 Group
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Arm description:

Subjects in the Cervarix Group of the primary study (NCT00196924), who had then received 3 doses of Cervarix™ vaccine intramuscularly into the deltoid region of the non-dominant arm according to a 0, 1, 6 month vaccination schedule.

Arm type	Experimental
Investigational medicinal product name	Cervarix™
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

All subjects received 3 doses of HPV vaccine intramuscularly into the deltoid region of the non-dominant arm.

Number of subjects in period 1^[1]	Cervarix Month 60 Group
Started	397
Completed	397

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: Subjects not returning for a specific visit were not withdrawn and could participate in the subsequent follow-up phases. Actual enrolment differed depending on the rate of return for the follow-up study, so not all enrolled subjects came to each visit.

Period 2

Period 2 title	Month 72
Is this the baseline period?	No
Allocation method	Randomised - controlled
Blinding used	Not blinded

Arms

Arm title	Cervarix Month 72 Group
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Arm description:

Subjects in the Cervarix Group of the primary study (NCT00196924), who had then received 3 doses of Cervarix™ vaccine intramuscularly into the deltoid region of the non-dominant arm according to a 0, 1, 6 month vaccination schedule.

Arm type	Experimental
Investigational medicinal product name	Cervarix™
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

All subjects received 3 doses of HPV vaccine intramuscularly into the deltoid region of the non-dominant arm.

Number of subjects in period 2	Cervarix Month 72 Group
Started	397
Completed	529

Joined	132
Subject inconsistency in coming to study visits	132

Period 3

Period 3 title	Month 84
Is this the baseline period?	No
Allocation method	Randomised - controlled
Blinding used	Not blinded

Arms

Arm title	Cervarix Month 84 Group
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Arm description:

Subjects in the Cervarix Group of the primary study (NCT00196924), who had then received 3 doses of Cervarix™ vaccine intramuscularly into the deltoid region of the non-dominant arm according to a 0, 1, 6 month vaccination schedule.

Arm type	Experimental
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Investigational medicinal product name	Cervarix™
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

All subjects received 3 doses of HPV vaccine intramuscularly into the deltoid region of the non-dominant arm.

Number of subjects in period 3^[2]	Cervarix Month 84 Group
Started	523
Completed	523

Notes:

[2] - The number of subjects starting the period is not consistent with the number completing the preceding period. It is expected the number of subjects starting the subsequent period will be the same as the number completing the preceding period.

Justification: Subjects not returning for a specific visit were not withdrawn and could participate in the subsequent follow-up phases. Actual enrolment differed depending on the rate of return for the follow-up study, so not all enrolled subjects came to each visit.

Period 4

Period 4 title	Month 96
Is this the baseline period?	No
Allocation method	Randomised - controlled
Blinding used	Not blinded

Arms

Arm title	Cervarix Month 96 Group
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Arm description:

Subjects in the Cervarix Group of the primary study (NCT00196924), who had then received 3 doses of Cervarix™ vaccine intramuscularly into the deltoid region of the non-dominant arm according to a 0, 1, 6 month vaccination schedule.

Arm type	Experimental
Investigational medicinal product name	Cervarix™
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

All subjects received 3 doses of HPV vaccine intramuscularly into the deltoid region of the non-dominant arm.

Number of subjects in period 4^[3]	Cervarix Month 96 Group
Started	522
Completed	522

Notes:

[3] - The number of subjects starting the period is not consistent with the number completing the preceding period. It is expected the number of subjects starting the subsequent period will be the same as the number completing the preceding period.

Justification: Subjects not returning for a specific visit were not withdrawn and could participate in the subsequent follow-up phases. Actual enrolment differed depending on the rate of return for the follow-up study, so not all enrolled subjects came to each visit.

Period 5

Period 5 title	Month 108
Is this the baseline period?	No
Allocation method	Randomised - controlled
Blinding used	Not blinded

Arms

Arm title	Cervarix Month 108 Group
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Arm description:

Subjects in the Cervarix Group of the primary study (NCT00196924), who had then received 3 doses of Cervarix™ vaccine intramuscularly into the deltoid region of the non-dominant arm according to a 0, 1, 6 month vaccination schedule.

Arm type	Experimental
Investigational medicinal product name	Cervarix™
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

All subjects received 3 doses of HPV vaccine intramuscularly into the deltoid region of the non-dominant arm.

Number of subjects in period 5^[4]	Cervarix Month 108 Group
Started	507
Completed	507

Notes:

[4] - The number of subjects starting the period is not consistent with the number completing the preceding period. It is expected the number of subjects starting the subsequent period will be the same as the number completing the preceding period.

Justification: Subjects not returning for a specific visit were not withdrawn and could participate in the subsequent follow-up phases. Actual enrolment differed depending on the rate of return for the follow-up study, so not all enrolled subjects came to each visit.

Period 6

Period 6 title	Month 120
Is this the baseline period?	No
Allocation method	Randomised - controlled
Blinding used	Not blinded

Arms

Arm title	Cervarix Month 120 Group
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Arm description:

Subjects in the Cervarix Group of the primary study (NCT00196924), who had then received 3 doses of Cervarix™ vaccine intramuscularly into the deltoid region of the non-dominant arm according to a 0, 1, 6 month vaccination schedule.

Arm type	Experimental
Investigational medicinal product name	Cervarix™
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

All subjects received 3 doses of HPV vaccine intramuscularly into the deltoid region of the non-dominant arm.

Number of subjects in period 6^[5]	Cervarix Month 120 Group
Started	495
Completed	495

Notes:

[5] - The number of subjects starting the period is not consistent with the number completing the preceding period. It is expected the number of subjects starting the subsequent period will be the same as the number completing the preceding period.

Justification: Subjects not returning for a specific visit were not withdrawn and could participate in the subsequent follow-up phases. Actual enrolment differed depending on the rate of return for the follow-up study, so not all enrolled subjects came to each visit.

Baseline characteristics

Reporting groups

Reporting group title	Month 60
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Reporting group description: -

Reporting group values	Month 60	Total	
Number of subjects	397	397	
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			
arithmetic mean	17.1		
standard deviation	± 1.4	-	
Gender categorical			
Units: Subjects			
Female	397	397	
Male	0	0	

End points

End points reporting groups

Reporting group title	Cervarix Month 60 Group
Reporting group description: Subjects in the Cervarix Group of the primary study (NCT00196924), who had then received 3 doses of Cervarix™ vaccine intramuscularly into the deltoid region of the non-dominant arm according to a 0, 1, 6 month vaccination schedule.	
Reporting group title	Cervarix Month 72 Group
Reporting group description: Subjects in the Cervarix Group of the primary study (NCT00196924), who had then received 3 doses of Cervarix™ vaccine intramuscularly into the deltoid region of the non-dominant arm according to a 0, 1, 6 month vaccination schedule.	
Reporting group title	Cervarix Month 84 Group
Reporting group description: Subjects in the Cervarix Group of the primary study (NCT00196924), who had then received 3 doses of Cervarix™ vaccine intramuscularly into the deltoid region of the non-dominant arm according to a 0, 1, 6 month vaccination schedule.	
Reporting group title	Cervarix Month 96 Group
Reporting group description: Subjects in the Cervarix Group of the primary study (NCT00196924), who had then received 3 doses of Cervarix™ vaccine intramuscularly into the deltoid region of the non-dominant arm according to a 0, 1, 6 month vaccination schedule.	
Reporting group title	Cervarix Month 108 Group
Reporting group description: Subjects in the Cervarix Group of the primary study (NCT00196924), who had then received 3 doses of Cervarix™ vaccine intramuscularly into the deltoid region of the non-dominant arm according to a 0, 1, 6 month vaccination schedule.	
Reporting group title	Cervarix Month 120 Group
Reporting group description: Subjects in the Cervarix Group of the primary study (NCT00196924), who had then received 3 doses of Cervarix™ vaccine intramuscularly into the deltoid region of the non-dominant arm according to a 0, 1, 6 month vaccination schedule.	

Primary: Number of seroconverted subjects with anti-HPV-16 antibody titers equal to or above 8 EL.U/mL

End point title	Number of seroconverted subjects with anti-HPV-16 antibody titers equal to or above 8 EL.U/mL ^[1]
End point description: Anti-HPV-16 assay cut-off value was defined as 8 ELISA units per milliliter (EL.U/mL). Anti-HPV-18 assay cut-off value was defined as 7 EL.U/mL. Seroconversion was defined as the appearance of antibodies (i.e. titer greater than or equal to the cut-off value) in the serum of subjects seronegative before vaccination. A seronegative subject is a subject with antibody titer < 8 or 7 EL.U/mL prior to vaccination. A seropositive subject is a subject with antibody titer ≥ 8 or 7 EL.U/mL prior to vaccination.	
End point type	Primary
End point timeframe: At Months 60, 72, 84, 96 and 108	
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 scope of this primary endpoint was descriptive, no statistical analyses were conducted.	

End point values	Cervarix Month 96 Group	Cervarix Month 84 Group	Cervarix Month 72 Group	Cervarix Month 60 Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	473	475	469	353
Units: Subjects				
anti-HPV-16	473	475	469	353

End point values	Cervarix Month 108 Group			
Subject group type	Reporting group			
Number of subjects analysed	374			
Units: Subjects				
anti-HPV-16	372			

Statistical analyses

No statistical analyses for this end point

Primary: Number of seroconverted subjects with anti-HPV-18 antibody titers equal to or above 7 EL.U/mL

End point title	Number of seroconverted subjects with anti-HPV-18 antibody titers equal to or above 7 EL.U/mL ^[2]
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End point description:

Anti-HPV-16 assay cut-off value was defined as 8 ELISA units per milliliter (EL.U/mL). Anti-HPV-18 assay cut-off value was defined as 7 EL.U/mL. Seroconversion was defined as the appearance of antibodies (i.e. titer greater than or equal to the cut-off value) in the serum of subjects seronegative before vaccination. A seronegative subject is a subject with antibody titer < 8 or 7 EL.U/mL prior to vaccination. A seropositive subject is a subject with antibody titer ≥ 8 or 7 EL.U/mL prior to vaccination.

End point type	Primary
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End point timeframe:

At Months 60, 72, 84, 96 and 108

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 scope of this primary endpoint was descriptive, no statistical analyses were conducted.

End point values	Cervarix Month 96 Group	Cervarix Month 84 Group	Cervarix Month 72 Group	Cervarix Month 60 Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	477	473	478	358
Units: Subjects				
anti-HPV-18	477	473	478	358

End point values	Cervarix Month 108 Group			
Subject group type	Reporting group			
Number of subjects analysed	370			

Units: Subjects				
anti-HPV-18	368			

Statistical analyses

No statistical analyses for this end point

Primary: Anti-human papillomavirus-16 (anti-HPV-16) antibody titers

End point title	Anti-human papillomavirus-16 (anti-HPV-16) antibody titers ^[3]
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End point description:

Anti-HPV-16 and 18 antibody titers are given in Geometric Mean Titers (GMTs) in Enzyme-linked Immunosorbent Assay (ELISA) Units per milliliter (EL.U/mL).

End point type	Primary
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End point timeframe:

At Months 60, 72, 84, 96 and 108

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 scope of this primary endpoint was descriptive, no statistical analyses were conducted.

End point values	Cervarix Month 96 Group	Cervarix Month 84 Group	Cervarix Month 72 Group	Cervarix Month 60 Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	499	494	502	376
Units: EL.U/mL				
geometric mean (confidence interval 95%)				
anti-HPV-16	1671 (1548.1 to 1803.7)	1756.7 (1622.7 to 1901.7)	1973.9 (1827.9 to 2131.6)	2262.9 (2069.1 to 2475)

End point values	Cervarix Month 108 Group			
Subject group type	Reporting group			
Number of subjects analysed	392			
Units: EL.U/mL				
geometric mean (confidence interval 95%)				
anti-HPV-16	1946.5 (1779.7 to 2128.9)			

Statistical analyses

No statistical analyses for this end point

Primary: Anti-human papillomavirus-18 (anti-HPV-18) antibody titers

End point title	Anti-human papillomavirus-18 (anti-HPV-18) antibody titers ^[4]
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End point description:

Anti-HPV-16 and 18 antibody titers are given in Geometric Mean Titers (GMTs) in Enzyme-linked Immunosorbent Assay (ELISA) Units per milliliter (EL.U/mL).

End point type	Primary
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End point timeframe:

At months 60, 72, 84, 96 and 108

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 scope of this primary endpoint was descriptive, no statistical analyses were conducted.

End point values	Cervarix Month 96 Group	Cervarix Month 84 Group	Cervarix Month 72 Group	Cervarix Month 60 Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	499	494	502	376
Units: EL.U/mL				
geometric mean (confidence interval 95%)				
anti-HPV-18	679 (623.5 to 739.4)	609.7 (559 to 664.9)	762.8 (701 to 830.1)	778.6 (703.1 to 862.1)

End point values	Cervarix Month 108 Group			
Subject group type	Reporting group			
Number of subjects analysed	391			
Units: EL.U/mL				
geometric mean (confidence interval 95%)				
anti-HPV-18	754 (685.4 to 829.4)			

Statistical analyses

No statistical analyses for this end point

Primary: Number of subjects with serious adverse events (SAEs)

End point title	Number of subjects with serious adverse events (SAEs) ^[5]
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End point description:

SAEs assessed include medical occurrences that result in death, are life threatening, require hospitalization or prolongation of hospitalization, result in disability/incapacity or are a congenital anomaly/birth defect in the offspring of a study subject.

End point type	Primary
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End point timeframe:

From Month 48 to 60 (at Month 60), 60 to 72 (at Month 72), 72 to 84 (at Month 84), 84 to 96 (at Month 96), 96 to 108 (at Month 108), 108 to 120 (at Month 120).

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 scope of this primary endpoint was descriptive, no statistical analyses were conducted.

End point values	Cervarix Month 96 Group	Cervarix Month 84 Group	Cervarix Month 72 Group	Cervarix Month 60 Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	522	523	529	397
Units: Subjects				
SAEs	8	20	20	9

End point values	Cervarix Month 108 Group	Cervarix Month 120 Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	507	495		
Units: Subjects				
SAEs	15	6		

Statistical analyses

No statistical analyses for this end point

Primary: Anti-HPV-16 antibody titers

End point title	Anti-HPV-16 antibody titers ^[6]
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End point description:

Anti-HPV-16 assay cut-off value was defined as 8 ELISA units per milliliter (EL.U/mL). Anti-HPV-18 assay cut-off value was defined as 7 EL.U/mL. Seroconversion was defined as the appearance of antibodies (i.e. titer greater than or equal to the cut-off value) in the serum of subjects seronegative before vaccination. A seronegative subject is a subject with antibody titer < 8 or 7 EL.U/mL prior to vaccination. A seropositive subject is a subject with antibody titer ≥ 8 or 7 EL.U/mL prior to vaccination.

End point type	Primary
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End point timeframe:

At Month 120

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 scope of this primary endpoint was descriptive, no statistical analyses were conducted.

End point values	Cervarix Month 120 Group			
Subject group type	Reporting group			
Number of subjects analysed	416			
Units: EL.U/mL				
geometric mean (confidence interval 95%)				
Anti-HPV-16	1607.9 (1480.8 to 1746.1)			

Statistical analyses

No statistical analyses for this end point

Primary: Number of seroconverted subjects with HPV-16 antibody titers ≥ 8 EL.U/mL

End point title	Number of seroconverted subjects with HPV-16 antibody titers ≥ 8 EL.U/mL ^[7]
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End point description:

Anti-HPV-16 assay cut-off value was defined as 8 ELISA units per milliliter (EL.U/mL). Anti-HPV-18 assay cut-off value was defined as 7 EL.U/mL. Seroconversion was defined as the appearance of antibodies (i.e. titer greater than or equal to the cut-off value) in the serum of subjects seronegative before vaccination. A seronegative subject is a subject with antibody titer < 8 or 7 EL.U/mL prior to vaccination. A seropositive subject is a subject with antibody titer ≥ 8 or 7 EL.U/mL prior to vaccination.

End point type	Primary
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End point timeframe:

At Month 120

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 scope of this primary endpoint was descriptive, no statistical analyses were conducted.

End point values	Cervarix Month 120 Group			
Subject group type	Reporting group			
Number of subjects analysed	393			
Units: Subjects				
Anti-HPV-16	393			

Statistical analyses

No statistical analyses for this end point

Primary: Number of seroconverted subjects with HPV-18 antibody titers ≥ 7 EL.U/mL

End point title	Number of seroconverted subjects with HPV-18 antibody titers ≥ 7 EL.U/mL ^[8]
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End point description:

Anti-HPV-16 assay cut-off value was defined as 8 ELISA units per milliliter (EL.U/mL). Anti-HPV-18 assay cut-off value was defined as 7 EL.U/mL. Seroconversion was defined as the appearance of antibodies (i.e. titer greater than or equal to the cut-off value) in the serum of subjects seronegative before vaccination. A seronegative subject is a subject with antibody titer < 8 or 7 EL.U/mL prior to vaccination. A seropositive subject is a subject with antibody titer ≥ 8 or 7 EL.U/mL prior to vaccination.

End point type	Primary
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End point timeframe:

At Month 120

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 scope of this primary endpoint was descriptive, no statistical analyses were conducted.

End point values	Cervarix Month 120 Group			
Subject group type	Reporting group			
Number of subjects analysed	395			
Units: Subjects				
Anti-HPV-18	395			

Statistical analyses

No statistical analyses for this end point

Primary: Anti-HPV-18 antibody titers

End point title	Anti-HPV-18 antibody titers ^[9]
End point description: Anti-HPV-16 assay cut-off value was defined as 8 ELISA units per milliliter (EL.U/mL). Anti-HPV-18 assay cut-off value was defined as 7 EL.U/mL. Seroconversion was defined as the appearance of antibodies (i.e. titer greater than or equal to the cut-off value) in the serum of subjects seronegative before vaccination. A seronegative subject is a subject with antibody titer < 8 or 7 EL.U/mL prior to vaccination. A seropositive subject is a subject with antibody titer ≥ 8 or 7 EL.U/mL prior to vaccination.	
End point type	Primary
End point timeframe: At Month 120	

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 scope of this primary endpoint was descriptive, no statistical analyses were conducted.

End point values	Cervarix Month 120 Group			
Subject group type	Reporting group			
Number of subjects analysed	415			
Units: EL.U/mL				
geometric mean (confidence interval 95%)				
Anti-HPV-18	608 (552.5 to 669.1)			

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information^[1]

Timeframe for reporting adverse events:

Serious Adverse Events were assessed by time intervals: Months 48-60, Months 60-72, Months 72-84, Months 84-96, Months 96-108 and Months 108-120.

Adverse event reporting additional description:

Other (non-serious) Adverse Events were not collected/assessed during this long-term follow-up study.

Assessment type	Non-systematic
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Dictionary used

Dictionary name	MedDRA
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Dictionary version	18.0
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Reporting groups

Reporting group title	Cervarix Group from Month 48 until Month 60
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Reporting group description:

Subjects in the Cervarix Group of the primary study (NCT00196924), who had then received 3 doses of Cervarix™ vaccine intramuscularly into the deltoid region of the non-dominant arm according to a 0, 1, 6 month vaccination schedule and for whom serious adverse events were collected from Month 48 until Month 60.

Reporting group title	Cervarix Group from Month 60 until Month 72
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Reporting group description:

Subjects in the Cervarix Group of the primary study (NCT00196924), who had then received 3 doses of Cervarix™ vaccine intramuscularly into the deltoid region of the non-dominant arm according to a 0, 1, 6 month vaccination schedule and for whom serious adverse events were collected from Month 60 until Month 72.

Reporting group title	Cervarix Group from Month 72 to Month 84
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Reporting group description:

Subjects in the Cervarix Group of the primary study (NCT00196924), who had then received 3 doses of Cervarix™ vaccine intramuscularly into the deltoid region of the non-dominant arm according to a 0, 1, 6 month vaccination schedule and for whom serious adverse events were collected from Month 72 until Month 84.

Reporting group title	Cervarix Group from Month 84 to Month 96
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Reporting group description:

Subjects in the Cervarix Group of the primary study (NCT00196924), who had then received 3 doses of Cervarix™ vaccine intramuscularly into the deltoid region of the non-dominant arm according to a 0, 1, 6 month vaccination schedule and for whom serious adverse events were collected from Month 84 until Month 96.

Reporting group title	Cervarix Group from Month 96 to Month 108
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Reporting group description:

Subjects in the Cervarix Group of the primary study (NCT00196924), who had then received 3 doses of Cervarix™ vaccine intramuscularly into the deltoid region of the non-dominant arm according to a 0, 1, 6 month vaccination schedule and for whom serious adverse events were collected from Month 96 until Month 108.

Reporting group title	Cervarix Group from Month 108 to Month 120
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Reporting group description:

Subjects in the Cervarix Group of the primary study (NCT00196924), who had then received 3 doses of Cervarix™ vaccine intramuscularly into the deltoid region of the non-dominant arm according to a 0, 1, 6 month vaccination schedule and for whom serious adverse events were collected from Month 108 to Month 120.

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: Only serious adverse event were collected for this study.

Serious adverse events	Cervarix Group from Month 48 until Month 60	Cervarix Group from Month 60 until Month 72	Cervarix Group from Month 72 to Month 84
Total subjects affected by serious adverse events			
subjects affected / exposed	9 / 397 (2.27%)	20 / 529 (3.78%)	20 / 523 (3.82%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Ovarian germ cell teratoma benign			
subjects affected / exposed	0 / 397 (0.00%)	1 / 529 (0.19%)	0 / 523 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fibroadenoma of breast			
subjects affected / exposed	0 / 397 (0.00%)	0 / 529 (0.00%)	1 / 523 (0.19%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ovarian neoplasm			
subjects affected / exposed	0 / 397 (0.00%)	0 / 529 (0.00%)	0 / 523 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hodgkin's disease			
subjects affected / exposed	0 / 397 (0.00%)	0 / 529 (0.00%)	0 / 523 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
Circulatory collapse			
subjects affected / exposed	0 / 397 (0.00%)	1 / 529 (0.19%)	0 / 523 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypertension			
subjects affected / exposed	0 / 397 (0.00%)	0 / 529 (0.00%)	0 / 523 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypovolaemic shock			

subjects affected / exposed	0 / 397 (0.00%)	0 / 529 (0.00%)	0 / 523 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Surgical and medical procedures			
Abortion induced			
subjects affected / exposed	0 / 397 (0.00%)	0 / 529 (0.00%)	1 / 523 (0.19%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pregnancy, puerperium and perinatal conditions			
Abortion spontaneous complete			
subjects affected / exposed	1 / 397 (0.25%)	0 / 529 (0.00%)	0 / 523 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abortion spontaneous incomplete			
subjects affected / exposed	1 / 397 (0.25%)	3 / 529 (0.57%)	2 / 523 (0.38%)
occurrences causally related to treatment / all	0 / 1	0 / 3	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Threatened labour			
subjects affected / exposed	1 / 397 (0.25%)	1 / 529 (0.19%)	0 / 523 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pre-eclampsia			
subjects affected / exposed	0 / 397 (0.00%)	1 / 529 (0.19%)	0 / 523 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oligohydramnios			
subjects affected / exposed	0 / 397 (0.00%)	0 / 529 (0.00%)	2 / 523 (0.38%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Foetal death			
subjects affected / exposed	0 / 397 (0.00%)	0 / 529 (0.00%)	1 / 523 (0.19%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Cervical incompetence			
subjects affected / exposed	0 / 397 (0.00%)	0 / 529 (0.00%)	0 / 523 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gestational diabetes			
subjects affected / exposed	0 / 397 (0.00%)	0 / 529 (0.00%)	0 / 523 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abortion spontaneous			
subjects affected / exposed	0 / 397 (0.00%)	0 / 529 (0.00%)	0 / 523 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ectopic pregnancy			
subjects affected / exposed	0 / 397 (0.00%)	0 / 529 (0.00%)	0 / 523 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Premature baby			
subjects affected / exposed	0 / 397 (0.00%)	0 / 529 (0.00%)	0 / 523 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Stillbirth			
subjects affected / exposed	0 / 397 (0.00%)	0 / 529 (0.00%)	0 / 523 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
Pain			
subjects affected / exposed	0 / 397 (0.00%)	1 / 529 (0.19%)	0 / 523 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Reproductive system and breast disorders			
Ovarian cyst			

subjects affected / exposed	1 / 397 (0.25%)	0 / 529 (0.00%)	0 / 523 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ovarian cyst ruptured			
subjects affected / exposed	0 / 397 (0.00%)	0 / 529 (0.00%)	0 / 523 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neonatal tachypnoea			
subjects affected / exposed	0 / 397 (0.00%)	0 / 529 (0.00%)	0 / 523 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Inguinal hernia			
subjects affected / exposed	0 / 397 (0.00%)	0 / 529 (0.00%)	0 / 523 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Neonatal asphyxia			
subjects affected / exposed	0 / 397 (0.00%)	0 / 529 (0.00%)	0 / 523 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neonatal respiratory distress syndrome			
subjects affected / exposed	0 / 397 (0.00%)	0 / 529 (0.00%)	0 / 523 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
Suicide attempt			
subjects affected / exposed	0 / 397 (0.00%)	1 / 529 (0.19%)	0 / 523 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Depression			
subjects affected / exposed	0 / 397 (0.00%)	0 / 529 (0.00%)	1 / 523 (0.19%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Drug abuse			
subjects affected / exposed	0 / 397 (0.00%)	0 / 529 (0.00%)	0 / 523 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Alcohol poisoning			
subjects affected / exposed	0 / 397 (0.00%)	1 / 529 (0.19%)	0 / 523 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Burns third degree			
subjects affected / exposed	0 / 397 (0.00%)	1 / 529 (0.19%)	0 / 523 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Multiple injuries			
subjects affected / exposed	0 / 397 (0.00%)	1 / 529 (0.19%)	2 / 523 (0.38%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Joint dislocation			
subjects affected / exposed	0 / 397 (0.00%)	0 / 529 (0.00%)	1 / 523 (0.19%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Stab wound			
subjects affected / exposed	0 / 397 (0.00%)	0 / 529 (0.00%)	1 / 523 (0.19%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal injury			
subjects affected / exposed	0 / 397 (0.00%)	0 / 529 (0.00%)	0 / 523 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ligament rupture			
subjects affected / exposed	0 / 397 (0.00%)	0 / 529 (0.00%)	0 / 523 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Contusion			
subjects affected / exposed	0 / 397 (0.00%)	0 / 529 (0.00%)	0 / 523 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Excoriation			
subjects affected / exposed	0 / 397 (0.00%)	0 / 529 (0.00%)	0 / 523 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Congenital, familial and genetic disorders			
Skull malformation			
subjects affected / exposed	1 / 397 (0.25%)	0 / 529 (0.00%)	0 / 523 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Congenital megaureter			
subjects affected / exposed	0 / 397 (0.00%)	0 / 529 (0.00%)	1 / 523 (0.19%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Talipes			
subjects affected / exposed	0 / 397 (0.00%)	0 / 529 (0.00%)	1 / 523 (0.19%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Heart disease congenital			
subjects affected / exposed	0 / 397 (0.00%)	0 / 529 (0.00%)	0 / 523 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary malformation			
subjects affected / exposed	0 / 397 (0.00%)	0 / 529 (0.00%)	0 / 523 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Brain injury			
subjects affected / exposed	0 / 397 (0.00%)	1 / 529 (0.19%)	0 / 523 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Cerebral cyst			
subjects affected / exposed	0 / 397 (0.00%)	0 / 529 (0.00%)	1 / 523 (0.19%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Syncope			
subjects affected / exposed	0 / 397 (0.00%)	0 / 529 (0.00%)	0 / 523 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tension headache			
subjects affected / exposed	0 / 397 (0.00%)	0 / 529 (0.00%)	0 / 523 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Duodenal ulcer			
subjects affected / exposed	1 / 397 (0.25%)	0 / 529 (0.00%)	1 / 523 (0.19%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peritonitis			
subjects affected / exposed	0 / 397 (0.00%)	1 / 529 (0.19%)	0 / 523 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Crohn's disease			
subjects affected / exposed	0 / 397 (0.00%)	0 / 529 (0.00%)	1 / 523 (0.19%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diverticulum intestinal			
subjects affected / exposed	0 / 397 (0.00%)	0 / 529 (0.00%)	1 / 523 (0.19%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastritis			
subjects affected / exposed	0 / 397 (0.00%)	0 / 529 (0.00%)	1 / 523 (0.19%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Coeliac disease			

subjects affected / exposed	0 / 397 (0.00%)	0 / 529 (0.00%)	0 / 523 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Enteritis			
subjects affected / exposed	0 / 397 (0.00%)	0 / 529 (0.00%)	0 / 523 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Irritable bowel syndrome			
subjects affected / exposed	0 / 397 (0.00%)	0 / 529 (0.00%)	0 / 523 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
Hydronephrosis			
subjects affected / exposed	0 / 397 (0.00%)	0 / 529 (0.00%)	1 / 523 (0.19%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Abscess			
subjects affected / exposed	1 / 397 (0.25%)	0 / 529 (0.00%)	0 / 523 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Appendicitis			
subjects affected / exposed	1 / 397 (0.25%)	1 / 529 (0.19%)	1 / 523 (0.19%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cystitis			
subjects affected / exposed	1 / 397 (0.25%)	0 / 529 (0.00%)	0 / 523 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyelonephritis			
subjects affected / exposed	1 / 397 (0.25%)	0 / 529 (0.00%)	0 / 523 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dengue fever			

subjects affected / exposed	0 / 397 (0.00%)	2 / 529 (0.38%)	0 / 523 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pharyngeal abscess			
subjects affected / exposed	0 / 397 (0.00%)	2 / 529 (0.38%)	0 / 523 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Breast abscess			
subjects affected / exposed	0 / 397 (0.00%)	1 / 529 (0.19%)	0 / 523 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chronic sinusitis			
subjects affected / exposed	0 / 397 (0.00%)	1 / 529 (0.19%)	0 / 523 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Endometritis			
subjects affected / exposed	0 / 397 (0.00%)	1 / 529 (0.19%)	0 / 523 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Endometritis decidual			
subjects affected / exposed	0 / 397 (0.00%)	0 / 529 (0.00%)	1 / 523 (0.19%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis			
subjects affected / exposed	0 / 397 (0.00%)	0 / 529 (0.00%)	1 / 523 (0.19%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Upper respiratory tract infection			
subjects affected / exposed	0 / 397 (0.00%)	0 / 529 (0.00%)	1 / 523 (0.19%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract infection			

subjects affected / exposed	0 / 397 (0.00%)	0 / 529 (0.00%)	0 / 523 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peritonsillar abscess			
subjects affected / exposed	0 / 397 (0.00%)	0 / 529 (0.00%)	0 / 523 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pilonidal cyst			
subjects affected / exposed	0 / 397 (0.00%)	0 / 529 (0.00%)	0 / 523 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Postoperative wound infection			
subjects affected / exposed	0 / 397 (0.00%)	0 / 529 (0.00%)	0 / 523 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia mycoplasmal			
subjects affected / exposed	0 / 397 (0.00%)	0 / 529 (0.00%)	0 / 523 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Type 1 diabetes mellitus			
subjects affected / exposed	0 / 397 (0.00%)	1 / 529 (0.19%)	0 / 523 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Cervarix Group from Month 84 to Month 96	Cervarix Group from Month 96 to Month 108	Cervarix Group from Month 108 to Month 120
Total subjects affected by serious adverse events			
subjects affected / exposed	8 / 522 (1.53%)	15 / 507 (2.96%)	6 / 495 (1.21%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Ovarian germ cell teratoma benign			

subjects affected / exposed	0 / 522 (0.00%)	0 / 507 (0.00%)	0 / 495 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fibroadenoma of breast			
subjects affected / exposed	0 / 522 (0.00%)	0 / 507 (0.00%)	0 / 495 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ovarian neoplasm			
subjects affected / exposed	0 / 522 (0.00%)	1 / 507 (0.20%)	0 / 495 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hodgkin's disease			
subjects affected / exposed	0 / 522 (0.00%)	0 / 507 (0.00%)	1 / 495 (0.20%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
Circulatory collapse			
subjects affected / exposed	0 / 522 (0.00%)	0 / 507 (0.00%)	0 / 495 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypertension			
subjects affected / exposed	1 / 522 (0.19%)	0 / 507 (0.00%)	0 / 495 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypovolaemic shock			
subjects affected / exposed	0 / 522 (0.00%)	1 / 507 (0.20%)	0 / 495 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Surgical and medical procedures			
Abortion induced			
subjects affected / exposed	0 / 522 (0.00%)	0 / 507 (0.00%)	0 / 495 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pregnancy, puerperium and perinatal			

conditions			
Abortion spontaneous complete			
subjects affected / exposed	0 / 522 (0.00%)	0 / 507 (0.00%)	0 / 495 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abortion spontaneous incomplete			
subjects affected / exposed	1 / 522 (0.19%)	0 / 507 (0.00%)	0 / 495 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Threatened labour			
subjects affected / exposed	0 / 522 (0.00%)	0 / 507 (0.00%)	0 / 495 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pre-eclampsia			
subjects affected / exposed	0 / 522 (0.00%)	1 / 507 (0.20%)	0 / 495 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oligohydramnios			
subjects affected / exposed	0 / 522 (0.00%)	0 / 507 (0.00%)	0 / 495 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Foetal death			
subjects affected / exposed	0 / 522 (0.00%)	0 / 507 (0.00%)	0 / 495 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cervical incompetence			
subjects affected / exposed	1 / 522 (0.19%)	0 / 507 (0.00%)	0 / 495 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gestational diabetes			
subjects affected / exposed	1 / 522 (0.19%)	0 / 507 (0.00%)	0 / 495 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abortion spontaneous			

subjects affected / exposed	0 / 522 (0.00%)	1 / 507 (0.20%)	0 / 495 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ectopic pregnancy			
subjects affected / exposed	0 / 522 (0.00%)	1 / 507 (0.20%)	1 / 495 (0.20%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Premature baby			
subjects affected / exposed	0 / 522 (0.00%)	1 / 507 (0.20%)	0 / 495 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Stillbirth			
subjects affected / exposed	0 / 522 (0.00%)	1 / 507 (0.20%)	0 / 495 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
Pain			
subjects affected / exposed	0 / 522 (0.00%)	0 / 507 (0.00%)	0 / 495 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Reproductive system and breast disorders			
Ovarian cyst			
subjects affected / exposed	0 / 522 (0.00%)	0 / 507 (0.00%)	0 / 495 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ovarian cyst ruptured			
subjects affected / exposed	0 / 522 (0.00%)	1 / 507 (0.20%)	0 / 495 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neonatal tachypnoea			
subjects affected / exposed	0 / 522 (0.00%)	1 / 507 (0.20%)	0 / 495 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Inguinal hernia			
subjects affected / exposed	0 / 522 (0.00%)	0 / 507 (0.00%)	1 / 495 (0.20%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Neonatal asphyxia			
subjects affected / exposed	0 / 522 (0.00%)	1 / 507 (0.20%)	0 / 495 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neonatal respiratory distress syndrome			
subjects affected / exposed	0 / 522 (0.00%)	1 / 507 (0.20%)	0 / 495 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
Suicide attempt			
subjects affected / exposed	1 / 522 (0.19%)	0 / 507 (0.00%)	0 / 495 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Depression			
subjects affected / exposed	0 / 522 (0.00%)	0 / 507 (0.00%)	0 / 495 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Drug abuse			
subjects affected / exposed	1 / 522 (0.19%)	0 / 507 (0.00%)	0 / 495 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Alcohol poisoning			
subjects affected / exposed	0 / 522 (0.00%)	0 / 507 (0.00%)	0 / 495 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Burns third degree			

subjects affected / exposed	0 / 522 (0.00%)	0 / 507 (0.00%)	0 / 495 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Multiple injuries			
subjects affected / exposed	0 / 522 (0.00%)	0 / 507 (0.00%)	0 / 495 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Joint dislocation			
subjects affected / exposed	0 / 522 (0.00%)	0 / 507 (0.00%)	0 / 495 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Stab wound			
subjects affected / exposed	0 / 522 (0.00%)	0 / 507 (0.00%)	0 / 495 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal injury			
subjects affected / exposed	1 / 522 (0.19%)	0 / 507 (0.00%)	0 / 495 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ligament rupture			
subjects affected / exposed	1 / 522 (0.19%)	0 / 507 (0.00%)	0 / 495 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Contusion			
subjects affected / exposed	0 / 522 (0.00%)	1 / 507 (0.20%)	0 / 495 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Excoriation			
subjects affected / exposed	0 / 522 (0.00%)	1 / 507 (0.20%)	0 / 495 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Congenital, familial and genetic disorders			
Skull malformation			

subjects affected / exposed	0 / 522 (0.00%)	0 / 507 (0.00%)	0 / 495 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Congenital megaureter			
subjects affected / exposed	0 / 522 (0.00%)	0 / 507 (0.00%)	0 / 495 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Talipes			
subjects affected / exposed	0 / 522 (0.00%)	0 / 507 (0.00%)	0 / 495 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Heart disease congenital			
subjects affected / exposed	0 / 522 (0.00%)	1 / 507 (0.20%)	0 / 495 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary malformation			
subjects affected / exposed	0 / 522 (0.00%)	1 / 507 (0.20%)	0 / 495 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Brain injury			
subjects affected / exposed	0 / 522 (0.00%)	0 / 507 (0.00%)	0 / 495 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebral cyst			
subjects affected / exposed	0 / 522 (0.00%)	0 / 507 (0.00%)	0 / 495 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Syncope			
subjects affected / exposed	0 / 522 (0.00%)	1 / 507 (0.20%)	0 / 495 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tension headache			

subjects affected / exposed	0 / 522 (0.00%)	1 / 507 (0.20%)	0 / 495 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Duodenal ulcer			
subjects affected / exposed	0 / 522 (0.00%)	0 / 507 (0.00%)	0 / 495 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peritonitis			
subjects affected / exposed	0 / 522 (0.00%)	0 / 507 (0.00%)	0 / 495 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Crohn's disease			
subjects affected / exposed	0 / 522 (0.00%)	0 / 507 (0.00%)	0 / 495 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diverticulum intestinal			
subjects affected / exposed	0 / 522 (0.00%)	0 / 507 (0.00%)	0 / 495 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastritis			
subjects affected / exposed	0 / 522 (0.00%)	0 / 507 (0.00%)	0 / 495 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Coeliac disease			
subjects affected / exposed	0 / 522 (0.00%)	1 / 507 (0.20%)	0 / 495 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Enteritis			
subjects affected / exposed	0 / 522 (0.00%)	1 / 507 (0.20%)	0 / 495 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Irritable bowel syndrome			

subjects affected / exposed	0 / 522 (0.00%)	0 / 507 (0.00%)	1 / 495 (0.20%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
Hydronephrosis			
subjects affected / exposed	0 / 522 (0.00%)	0 / 507 (0.00%)	0 / 495 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Abscess			
subjects affected / exposed	0 / 522 (0.00%)	0 / 507 (0.00%)	0 / 495 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Appendicitis			
subjects affected / exposed	0 / 522 (0.00%)	0 / 507 (0.00%)	0 / 495 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cystitis			
subjects affected / exposed	0 / 522 (0.00%)	0 / 507 (0.00%)	0 / 495 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyelonephritis			
subjects affected / exposed	0 / 522 (0.00%)	0 / 507 (0.00%)	0 / 495 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dengue fever			
subjects affected / exposed	0 / 522 (0.00%)	0 / 507 (0.00%)	0 / 495 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pharyngeal abscess			
subjects affected / exposed	0 / 522 (0.00%)	0 / 507 (0.00%)	0 / 495 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Breast abscess			

subjects affected / exposed	0 / 522 (0.00%)	0 / 507 (0.00%)	0 / 495 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chronic sinusitis			
subjects affected / exposed	0 / 522 (0.00%)	0 / 507 (0.00%)	0 / 495 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Endometritis			
subjects affected / exposed	0 / 522 (0.00%)	1 / 507 (0.20%)	0 / 495 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Endometritis decidual			
subjects affected / exposed	0 / 522 (0.00%)	0 / 507 (0.00%)	0 / 495 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis			
subjects affected / exposed	0 / 522 (0.00%)	0 / 507 (0.00%)	0 / 495 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Upper respiratory tract infection			
subjects affected / exposed	0 / 522 (0.00%)	0 / 507 (0.00%)	0 / 495 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract infection			
subjects affected / exposed	2 / 522 (0.38%)	0 / 507 (0.00%)	1 / 495 (0.20%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peritonsillar abscess			
subjects affected / exposed	1 / 522 (0.19%)	0 / 507 (0.00%)	0 / 495 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pilonidal cyst			

subjects affected / exposed	0 / 522 (0.00%)	1 / 507 (0.20%)	0 / 495 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Postoperative wound infection			
subjects affected / exposed	0 / 522 (0.00%)	1 / 507 (0.20%)	0 / 495 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia mycoplasmal			
subjects affected / exposed	0 / 522 (0.00%)	0 / 507 (0.00%)	1 / 495 (0.20%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Type 1 diabetes mellitus			
subjects affected / exposed	0 / 522 (0.00%)	0 / 507 (0.00%)	0 / 495 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

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

Non-serious adverse events	Cervarix Group from Month 48 until Month 60	Cervarix Group from Month 60 until Month 72	Cervarix Group from Month 72 to Month 84
Total subjects affected by non-serious adverse events			
subjects affected / exposed	0 / 397 (0.00%)	0 / 529 (0.00%)	0 / 523 (0.00%)

Non-serious adverse events	Cervarix Group from Month 84 to Month 96	Cervarix Group from Month 96 to Month 108	Cervarix Group from Month 108 to Month 120
Total subjects affected by non-serious adverse events			
subjects affected / exposed	0 / 522 (0.00%)	0 / 507 (0.00%)	0 / 495 (0.00%)

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
02 December 2013	The HPV-025 protocol was amended for the following reasons: The assay used to measure anti-HPV-16/-18 antibody concentrations at the designated laboratory was improved to increase the assay precision by changing the assay cut-off value from 8 EL.U/mL to 19 EL.U/mL for HPV-16 and from 7 EL.U/mL to 18 EL.U/mL for HPV-18. This change in the assay will be implemented for the testing of samples from Month 96 (Year 8) onwards. The number of subjects who were enrolled in the immunogenicity subset of the primary study HPV-013, received three doses of HPV vaccine and participated in the follow-up study Ext HPV-013 was erroneously mentioned as 626 subjects. This has now been corrected to 625 subjects. The total number of subjects in the Ext HPV-013 study was corrected to 1244 subjects.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported