Clinical trial results:
A phase IIIb, open, multi-centre gynaecological extension study for the follow-up of a subset of HPV-015 study subjects.

Summary

EudraCT number	2009-017282-35
Trial protocol	GB NL PT
Global end of trial date	20 September 2017

Results information

Result version number	v1 (current)
This version publication date	05 October 2018
First version publication date	05 October 2018

Trial information

Trial identification

Sponsor protocol code	113617

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT01190176
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, 44 2089904466, GSKClinicalSupportHD@gsk.com
Scientific contact	Clinical Trials Call Center, GlaxoSmithKline Biologicals, 44 2089904466, 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	27 December 2017
Is this the analysis of the primary completion data?	Yes
Primary completion date	20 September 2017
Global end of trial reached?	Yes
Global end of trial date	20 September 2017
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To provide clinical management and, if required, treatment to subjects who at their concluding HPV-015 study visit displayed normal cervical cytology but tested positive for oncogenic HPV infection or who were pregnant at their concluding visit of the HPV-015 study so that no cervical sample could be collected.

Note: Cervarix or Control [Al(OH)3] vaccines were administered in the HPV-015 (NCT00294047) primary study.
Subjects entered the HPV-062 study (current study) approximately one year after their HPV-015 (NCT00294047) concluding visit. Annual visits were scheduled for a maximum study duration of approximately four years in the current study.
At each visit in HPV-062 study, a gynaecological examination was performed and cervical liquid-based cytology samples were collected for cervical cytology examination and oncogenic HPV DNA testing, if the cytology reading was normal or atypical squamous cells of undetermined significance (ASC-US).

Protection of trial subjects:

The vaccinees will be observed closely for at least 30 minutes, with appropriate medical treatment readily available in case of anaphylaxis following the administration of vaccine.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	12 September 2011
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	No

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Canada: 11
Country: Number of subjects enrolled	Netherlands: 5
Country: Number of subjects enrolled	Portugal: 7
Country: Number of subjects enrolled	Russian Federation: 2
Country: Number of subjects enrolled	Singapore: 2
Country: Number of subjects enrolled	United Kingdom: 4
Country: Number of subjects enrolled	United States: 3
Worldwide total number of subjects	34
EEA total number of subjects	16

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)	34
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

This study was conducted by multiple investigators at 20 centres in Canada, Netherlands, Portugal, Russian Federation, Singapore, United Kingdom and the United States.

Pre-assignment

Screening details:

Although 34 subjects were enrolled in the study, 2 were excluded following eligibility criteria, leading to 32 subjects who started the study.

Period 1

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

Arms

Arm title	HPV-062 study subjects Group

Arm description:

HPV-015 (NCT00294047) study subjects who had normal cervical cytology, but tested positive for oncogenic HPV infection at their concluding HPV-015 (NCT00294047) study visit or were pregnant, so that no cervical sample could be collected at their concluding HPV-015 (NCT00294047) study visit.

Arm type	Experimental
Investigational medicinal product name	Cervarix
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Suspension for injection
Routes of administration	Intramuscular use

Dosage and administration details:

HPV-015 (NCT00294047) subjects received three doses of the study vaccine administered intramuscularly, according to a 0, 1, 6-month vaccination schedule in the primary study.

Investigational medicinal product name	Aluminium Hydroxide [Al(OH)3]
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Suspension for injection
Routes of administration	Intramuscular use

Dosage and administration details:

HPV-015 (NCT00294047) subjects received three doses of the control vaccine administered intramuscularly, according to a 0, 1, 6 month-vaccination schedule in the primary study.

Number of subjects in period 1[1]	HPV-062 study subjects Group
Started	32
Completed	30
Not completed	2
Consent withdrawn by subject	1
Lost to follow-up	1

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: Although 34 subjects were enrolled in the study, 2 were excluded following eligibility criteria, leading to 32 subjects who started the study.

Baseline characteristics

Reporting groups	
Reporting group title	HPV-062 study subjects Group
Reporting group description:	
HPV-015 (NCT00294047) study subjects who had normal cervical cytology, but tested positive for oncogenic HPV infection at their concluding HPV-015 (NCT00294047) study visit or were pregnant, so that no cervical sample could be collected at their concluding HPV-015 (NCT00294047) study visit.	

Reporting group values	HPV-062 study subjects Group	Total	
Number of subjects	32	32	
Age categorical Units: Subjects			
In utero	0	0	
Preterm newborn infants (gestational age < 37 wks)	0	0	
Newborns (0-27 days)	0	0	
Infants and toddlers (28 days-23 months)	0	0	
Children (2-11 years)	0	0	
Adolescents (12-17 years)	0	0	
Adults (18-64 years)	32	32	
From 65-84 years	0	0	
85 years and over	0	0	
Age continuous Units: years			
arithmetic mean	39.3		
standard deviation	± 6.3	-	
Gender categorical Units: Subjects			
Female	32	32	
Male	0	0	
Race/Ethnicity, Customized Units: Subjects			
White - Caucasian / European Heritage	28	28	
Asian - South East Asian Heritage	2	2	
African Heritage / African American	1	1	
American Indian or Alaskan Native	1	1	

End points

End points reporting groups

Reporting group title	HPV-062 study subjects Group

Reporting group description:

HPV-015 (NCT00294047) study subjects who had normal cervical cytology, but tested positive for oncogenic HPV infection at their concluding HPV-015 (NCT00294047) study visit or were pregnant, so that no cervical sample could be collected at their concluding HPV-015 (NCT00294047) study visit.

Primary: Number of subjects reporting positive oncogenic HPV DNA results by Hybrid Capture II test (HCII) at Month 12

End point title	Number of subjects reporting positive oncogenic HPV DNA results by Hybrid Capture II test (HCII) at Month 12[1]

End point description:

Subjects with 2 positive oncogenic HPV DNA tests or 1 cervical cytology reading ≥ ASC-US (atypical squamous cells of undetermined significance) positive for oncogenic HPV DNA or 1 cervical cytology reading ≥ LSIL (low grade squamous intraepithelial lesion) were referred for colposcopy evaluation according to the clinical management algorithm.

End point type	Primary

End point timeframe:

At Month 12 [12 months post concluding HPV-015 visit (Visit 9, Visit 11 or last HPV-015 study visit)]

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 end point was descriptive, hence no statistical hypothesis test was performed.

End point values	HPV-062 study subjects Group			
Subject group type	Reporting group			
Number of subjects analysed	13			
Units: Subjects				
Subjects	2			

Statistical analyses

No statistical analyses for this end point

Primary: Number of subjects reporting positive oncogenic HPV DNA results by Hybrid Capture II test (HCII) at Month 24

End point title	Number of subjects reporting positive oncogenic HPV DNA results by Hybrid Capture II test (HCII) at Month 24[2]

End point description:

Subjects with 2 positive oncogenic HPV DNA tests or 1 cervical cytology reading ≥ ASC-US (atypical squamous cells of undetermined significance) positive for oncogenic HPV DNA or 1 cervical cytology reading ≥ LSIL (low grade squamous intraepithelial lesion) were referred for colposcopy evaluation according to the clinical management algorithm.

End point type	Primary

End point timeframe:

At Month 24 [24 months post concluding HPV-015 visit (Visit 9, Visit 11 or last HPV-015 study visit)]

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 end point was descriptive, hence no statistical hypothesis test was performed.

End point values	HPV-062 study subjects Group			
Subject group type	Reporting group			
Number of subjects analysed	12			
Units: Subjects				
Subjects	3			

Statistical analyses

No statistical analyses for this end point

Primary: Number of subjects reporting positive oncogenic HPV DNA results by Hybrid Capture II test (HCII) at Month 36

End point title	Number of subjects reporting positive oncogenic HPV DNA results by Hybrid Capture II test (HCII) at Month 36[3]

End point description:

Subjects with 2 positive oncogenic HPV DNA tests or 1 cervical cytology reading ≥ ASC-US (atypical squamous cells of undetermined significance) positive for oncogenic HPV DNA or 1 cervical cytology reading ≥ LSIL (low grade squamous intraepithelial lesion) were referred for colposcopy evaluation according to the clinical management algorithm.

End point type	Primary

End point timeframe:

At Month 36 [36 months post concluding HPV-015 visit (Visit 9, Visit 11 or last HPV-015 study visit)]

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 end point was descriptive, hence no statistical hypothesis test was performed.

End point values	HPV-062 study subjects Group			
Subject group type	Reporting group			
Number of subjects analysed	9			
Units: Subjects				
Subjects	3			

Statistical analyses

No statistical analyses for this end point

Primary: Number of subjects reporting positive oncogenic HPV DNA results by Hybrid Capture II test (HCII) at Month 48

End point title	Number of subjects reporting positive oncogenic HPV DNA results by Hybrid Capture II test (HCII) at Month 48[4]

End point description:

Subjects with 2 positive oncogenic HPV DNA tests or 1 cervical cytology reading ≥ASC-US (atypical squamous cells of undetermined significance) positive for oncogenic HPV DNA or 1 cervical cytology reading ≥LSIL (low grade squamous intraepithelial lesion) were referred for colposcopy evaluation according to the clinical management algorithm.

End point type	Primary

End point timeframe:

At Month 48 [48 months post concluding HPV-015 visit (Visit 9, Visit 11 or last HPV-015 study visit)]

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 end point was descriptive, hence no statistical hypothesis test was performed.

End point values	HPV-062 study subjects Group			
Subject group type	Reporting group			
Number of subjects analysed	6			
Units: Subjects				
Subjects	1			

Statistical analyses

No statistical analyses for this end point

Primary: Number of subjects with any cytological abnormalities in cervical samples by ThinPrep PapTest at Month 12

End point title	Number of subjects with any cytological abnormalities in cervical samples by ThinPrep PapTest at Month 12[5]

End point description:

Cytological abnormalities = atypical squamous cells of undetermined significance (ASC-US). Cervical cytology was performed using the ThinPrep PapTest by Quest Diagnostics, or another GSK designated laboratory. Cervical cells for ThinPrep cytology were collected using the sampling device provided and rinsed into a collection vial containing PreservCyt medium.

End point type	Primary

End point timeframe:

At Month 12 [12 months post concluding HPV-015 visit (Visit 9, Visit 11 or last HPV-015 study visit)]

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 end point was descriptive, hence no statistical hypothesis test was performed.

End point values	HPV-062 study subjects Group			
Subject group type	Reporting group			
Number of subjects analysed	15			
Units: Subjects				
Normal	11			
ASC-US	2			
LSIL	2			

Statistical analyses

No statistical analyses for this end point

Primary: Number of subjects with any cytological abnormalities in cervical samples by ThinPrep PapTest at Month 24

End point title	Number of subjects with any cytological abnormalities in cervical samples by ThinPrep PapTest at Month 24[6]

End point description:

Cytological abnormalities = atypical squamous cells of undetermined significance (ASC-US). Cervical cytology was performed using the ThinPrep PapTest by Quest Diagnostics, or another GSK designated laboratory. Cervical cells for ThinPrep cytology were collected using the sampling device provided and rinsed into a collection vial containing PreservCyt medium.

End point type	Primary

End point timeframe:

At Month 24 [24 months post concluding HPV-015 visit (Visit 9, Visit 11 or last HPV-015 study visit)]

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 end point was descriptive, hence no statistical hypothesis test was performed.

End point values	HPV-062 study subjects Group			
Subject group type	Reporting group			
Number of subjects analysed	12			
Units: Subjects				
Normal	11			
ASC-US	1			
LSIL	0			

Statistical analyses

No statistical analyses for this end point

Primary: Number of subjects with any cytological abnormalities in cervical samples by ThinPrep PapTest at Month 36

End point title	Number of subjects with any cytological abnormalities in cervical samples by ThinPrep PapTest at Month 36[7]

End point description:

Cytological abnormalities = atypical squamous cells of undetermined significance (ASC-US). Cervical cytology was performed using the ThinPrep PapTest by Quest Diagnostics, or another GSK designated laboratory. Cervical cells for ThinPrep cytology were collected using the sampling device provided and rinsed into a collection vial containing PreservCyt medium.

End point type	Primary

End point timeframe:

At Month 36 [36 months post concluding HPV-015 visit (Visit 9, Visit 11 or last HPV-015 study visit)]

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 end point was descriptive, hence no statistical hypothesis test was performed.

End point values	HPV-062 study subjects Group			
Subject group type	Reporting group			
Number of subjects analysed	9			
Units: Subjects				
Normal	8			
ASC-US	1			
LSIL	0			

Statistical analyses

No statistical analyses for this end point

Primary: Number of subjects with any cytological abnormalities in cervical samples by ThinPrep PapTest at Month 48

End point title	Number of subjects with any cytological abnormalities in cervical samples by ThinPrep PapTest at Month 48[8]

End point description:

Cytological abnormalities = atypical squamous cells of undetermined significance (ASC-US). Cervical cytology was performed using the ThinPrep PapTest by Quest Diagnostics, or another GSK designated laboratory. Cervical cells for ThinPrep cytology were collected using the sampling device provided and rinsed into a collection vial containing PreservCyt medium.

End point type	Primary

End point timeframe:

At Month 48 [48 months post concluding HPV-015 visit (Visit 9, Visit 11 or last HPV-015 study visit)]

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 end point was descriptive, hence no statistical hypothesis test was performed.

End point values	HPV-062 study subjects Group			
Subject group type	Reporting group			
Number of subjects analysed	6			
Units: Subjects				
Normal	6			
ASC-US	0			
LSIL	0			

Statistical analyses

No statistical analyses for this end point

Primary: Number of subjects with referral to colposcopy at Month 12

End point title	Number of subjects with referral to colposcopy at Month 12[9]

End point description:

Detection was done on all subjects irrespective of their baseline HPV DNA status.

End point type	Primary

End point timeframe:

At Month 12 [12 months post concluding HPV-015 visit (Visit 9, Visit 11 or last HPV-015 study visit)]

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 end point was descriptive, hence no statistical hypothesis test was performed.

End point values	HPV-062 study subjects Group			
Subject group type	Reporting group			
Number of subjects analysed	15			
Units: Subjects				
Colposcopy referral - Yes (N=15)	4			
Colposcopy referral - No (N=15)	11			
Colposcopy performed - Yes (N=15)	4			
Colposcopy performed - No (N=15)	11			
Algorithm respected - Yes (N=4)	4			
Algorithm respected - No (N=4)	0			
Lesion - Yes (N=4)	1			
Lesion - No (N=4)	3			

Statistical analyses

No statistical analyses for this end point

Primary: Number of subjects with referral to colposcopy at Month 24

End point title	Number of subjects with referral to colposcopy at Month 24[10]

End point description:

Detection was done on all subjects irrespective of their baseline HPV DNA status.

End point type	Primary

End point timeframe:

At Month 24 [24 months post concluding HPV-015 visit (Visit 9, Visit 11 or last HPV-015 study visit)]

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 scope of this primary end point was descriptive, hence no statistical hypothesis test was performed.

End point values	HPV-062 study subjects Group			
Subject group type	Reporting group			
Number of subjects analysed	12			
Units: Subjects				
Colposcopy referral - Yes (N=12)	1			
Colposcopy referral - No (N=12)	11			
Colposcopy performed - Yes (N=12)	1			
Colposcopy performed - No (N=12)	11			
Algorithm respected - Yes (N=1)	1			
Algorithm respected - No (N=1)	0			
Lesion - Yes (N=1)	0			
Lesion - No (N=1)	1			

Statistical analyses

No statistical analyses for this end point

Primary: Number of subjects with referral to colposcopy at Month 36

End point title	Number of subjects with referral to colposcopy at Month 36[11]

End point description:

Detection was done on all subjects irrespective of their baseline HPV DNA status.

End point type	Primary

End point timeframe:

At Month 36 [36 months post concluding HPV-015 visit (Visit 9, Visit 11 or last HPV-015 study visit)]

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 scope of this primary end point was descriptive, hence no statistical hypothesis test was performed.

End point values	HPV-062 study subjects Group			
Subject group type	Reporting group			
Number of subjects analysed	9			
Units: Subjects				
Colposcopy referral - Yes (N=9)	3			
Colposcopy referral - No (N=9)	6			
Colposcopy performed - Yes (N=9)	3			
Colposcopy performed - No (N=9)	6			
Algorithm respected - Yes (N=3)	3			
Algorithm respected - No (N=3)	0			
Lesion - Yes (N=3)	0			
Lesion - No (N=3)	3			

Statistical analyses

No statistical analyses for this end point

Primary: Number of subjects with referral to colposcopy at Month 48

End point title	Number of subjects with referral to colposcopy at Month 48[12]

End point description:

Detection was done on all subjects irrespective of their baseline HPV DNA status.

End point type	Primary

End point timeframe:

At Month 48 [48 months post concluding HPV-015 visit (Visit 9, Visit 11 or last HPV-015 study visit)]

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 scope of this primary end point was descriptive, hence no statistical hypothesis test was performed.

End point values	HPV-062 study subjects Group			
Subject group type	Reporting group			
Number of subjects analysed	6			
Units: Subjects				
Colposcopy referral - Yes (N=6)	1			
Colposcopy referral - No (N=6)	5			
Colposcopy performed - Yes (N=6)	2			
Colposcopy performed - No (N=6)	4			
Algorithm respected - Yes (N=2)	1			
Algorithm respected - No (N=2)	1			
Lesion - Yes (N=2)	0			
Lesion - No (N=2)	2			

Statistical analyses

No statistical analyses for this end point

Primary: Number of subjects with referral to treatment at Month 12

End point title	Number of subjects with referral to treatment at Month 12[13]

End point description:

If a high-grade lesion was observed, the subject was referred to treatment according to local medical practice. Any further management following local cervical therapy for cervical lesions was handled according to local medical practice within the local health care system. After treatment, the subject's participation in the study ended.

End point type	Primary

End point timeframe:

At Month 12 [12 months post concluding HPV-015 visit (Visit 9, Visit 11 or last HPV-015 study visit)]

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 scope of this primary end point was descriptive, hence no statistical hypothesis test was performed.

End point values	HPV-062 study subjects Group			
Subject group type	Reporting group			
Number of subjects analysed	4			
Units: Subjects				
Treatment referral - Yes	0			
Treatment referral - No	4			
Treatment done - Yes	0			
Treatment done - No	4			

Statistical analyses

No statistical analyses for this end point

Primary: Number of subjects with referral to treatment at Month 24

End point title	Number of subjects with referral to treatment at Month 24[14]

End point description:

If a high-grade lesion was observed, the subject was referred to treatment according to local medical practice. Any further management following local cervical therapy for cervical lesions was handled according to local medical practice within the local health care system. After treatment, the subject's participation in the study ended.

End point type	Primary

End point timeframe:

At Month 24 [24 months post concluding HPV-015 visit (Visit 9, Visit 11 or last HPV-015 study visit)]

Notes:

[14] - 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 end point was descriptive, hence no statistical hypothesis test was performed.

End point values	HPV-062 study subjects Group			
Subject group type	Reporting group			
Number of subjects analysed	1			
Units: Subjects				
Treatment referral - Yes	0			
Treatment referral - No	1			
Treatment done - Yes	0			
Treatment done - No	1			

Statistical analyses

No statistical analyses for this end point

Primary: Number of subjects with referral to treatment at Month 36

End point title	Number of subjects with referral to treatment at Month 36[15]

End point description:

If a high-grade lesion was observed, the subject was referred to treatment according to local medical practice. Any further management following local cervical therapy for cervical lesions was handled

according to local medical practice within the local health care system. After treatment, the subject's participation in the study ended.

End point type	Primary

End point timeframe:

At Month 36 [36 months post concluding HPV-015 visit (Visit 9, Visit 11 or last HPV-015 study visit)]

Notes:

[15] - 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 end point was descriptive, hence no statistical hypothesis test was performed.

End point values	HPV-062 study subjects Group			
Subject group type	Reporting group			
Number of subjects analysed	3			
Units: Subjects				
Treatment referral - Yes (N=3)	1			
Treatment referral - No (N=3)	2			
Treatment done - Yes (N=3)	1			
Treatment done - No (N=3)	2			
Loop excision of cervix - Yes (N=1)	1			
Loop excision of cervix - No (N=1)	0			
Loop cone of cervix - Yes (N=1)	0			
Loop cone of cervix - No (N=1)	1			
Cold knife cone of cervix - Yes (N=1)	0			
Cold knife cone of cervix - No (N=1)	1			
Laser excision cone of cervix - Yes (N=1)	0			
Laser excision cone of cervix - No (N=1)	1			
Other - Yes (N=1)	0			
Other - No (N=1)	1			

Statistical analyses

No statistical analyses for this end point

Primary: Number of subjects with referral to treatment at Month 48

End point title	Number of subjects with referral to treatment at Month 48[16]

End point description:

If a high-grade lesion was observed, the subject was referred to treatment according to local medical practice. Any further management following local cervical therapy for cervical lesions was handled according to local medical practice within the local health care system. After treatment, the subject's participation in the study ended.

End point type	Primary

End point timeframe:

At Month 48 [48 months post concluding HPV-015 visit (Visit 9, Visit 11 or last HPV-015 study visit)]

Notes:

[16] - 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 end point was descriptive, hence no statistical hypothesis test was performed.

End point values	HPV-062 study subjects Group			
Subject group type	Reporting group			
Number of subjects analysed	2			
Units: Subjects				
Treatment referral - Yes	0			
Treatment referral - No	2			
Treatment done - Yes	0			
Treatment done - No	2			

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information[1]

Timeframe for reporting adverse events:

AEs and SAEs: During the entire study period [from 12 months after concluding HPV-015 (NCT00294047) study visit (Visit 9/Visit 11/Last visit) up to 48 months after concluding HPV-015 (NCT00294047) study visit (Visit 9/Visit 11/Last visit)].

Adverse event reporting additional description:

There were no adverse events (AEs) or serious adverse events (SAEs) reported during the entire study period.

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	20.1

Reporting groups

Reporting group title	HPV-062 study subjects Group

Reporting group description:

HPV-015 (NCT00294047) study subjects who had normal cervical cytology, but tested positive for oncogenic HPV infection at their concluding HPV-015 (NCT00294047) study visit or were pregnant, so that no cervical sample could be collected at their concluding HPV-015 (NCT00294047) study visit.

Serious adverse events	HPV-062 study subjects Group		
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 32 (0.00%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events	0		

Frequency threshold for reporting non-serious adverse events: 0 %

Non-serious adverse events	HPV-062 study subjects Group		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	0 / 32 (0.00%)		

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 (AEs) or serious adverse events (SAEs) reported during the entire study period.

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