Clinical trial results:
An observational follow up study of a randomised parallel group phase IV study to evaluate the duration of the immune response to vaccine and non-vaccine HPV types in UK adolescent females who received either Cervarix or Gardasil Human Papillomavirus (HPV) vaccines.

Summary

EudraCT number	2016-002083-13
Trial protocol	GB
Global end of trial date	31 August 2017

Results information

Result version number	v1 (current)
This version publication date	02 January 2019
First version publication date	02 January 2019

Trial information

Trial identification

Sponsor protocol code	HPV followup

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT02811068
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Public Health England
Sponsor organisation address	Manor Farm Road, Porton Down, Salisbury, United Kingdom, SP1 3QH
Public contact	Elizabeth Coates, Public Health England, 44 01980612922, elizabeth.coates@phe.gov.uk
Scientific contact	Elizabeth Coates, Public Health England, 44 01980612922, elizabeth.coates@phe.gov.uk

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	31 August 2018
Is this the analysis of the primary completion data?	Yes
Primary completion date	31 August 2017
Global end of trial reached?	Yes
Global end of trial date	31 August 2017
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

Technical version:
The measurement of antibody titres elicited to HPV vaccine and non-vaccine types following vaccination with either Cervarix or Gardasil 5-7 years post first immunisation and comparison between vaccines as well as over time.

Lay version:
To measure how much antibody is still present is in the blood of those vaccinated in our original study 5-7 years after they were vaccinated with either Cervarix or Gardisil HPV vaccines, including comparing the two groups with each other.

Protection of trial subjects:

Subjects will not be monitored in terms of safety outcomes as the study consists of a single visit requiring a blood draw. no investigational medicinal products will be given so it will not be necessary to collect safety data or to report adverse events.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	01 August 2016
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	United Kingdom: 58
Worldwide total number of subjects	58
EEA total number of subjects	58

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)	58
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

Subjects were recruited from a cohort of participants in a previous study, where participants had been randomised 1:1 to receive either the Cervarix or Gardasil vaccine in a three dose schedule, and provided blood samples at 1,2,7 and 12 months following the first dose to evaluate immunogenicity to vaccine and non-vaccine HPV genotypes.

Pre-assignment

Screening details:

absence of any bleeding disorders

Period 1

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

Arms

Are arms mutually exclusive?	Yes
Arm title	Subjects who received Cervarix in a previous clinical trial.

Arm description: -

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:

0.5ml

Investigational medicinal product name	GARDASIL
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Suspension for injection
Routes of administration	Intramuscular use

Dosage and administration details:

0.5ml

Arm title	Subjects who received Gardasil in a previous clinical trial

Arm description: -

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

Dosage and administration details:

0.5

Number of subjects in period 1	Subjects who received Cervarix in a previous clinical trial.	Subjects who received Gardasil in a previous clinical trial
Started	28	30
Completed	28	30

Baseline characteristics

Reporting groups	
Reporting group title	Entire trial period.

Reporting group description: -

Reporting group values	Entire trial period.	Total	
Number of subjects	58	58	
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)	58	58	
From 65-84 years	0	0	
85 years and over	0	0	
Gender categorical Units: Subjects			
Female	58	58	
Male	0	0	

End points

End points reporting groups

Reporting group title	Subjects who received Cervarix in a previous clinical trial.
Reporting group description: -	
Reporting group title	Subjects who received Gardasil in a previous clinical trial
Reporting group description: -	

Primary: Proportion with detectable titres at followup

End point title	Proportion with detectable titres at followup
End point description: Proportion positive for type 16	
End point type	Primary
End point timeframe: 7 yrs after vaccination	

End point values	Subjects who received Cervarix in a previous clinical trial.	Subjects who received Gardasil in a previous clinical trial		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	28	30		
Units: Integers	28	30		

Statistical analyses

Statistical analysis title	Pre Planned Analysis
Statistical analysis description: Groups will be compared by T-test on logged data or Kruskal-Wallis test as appropriate	
Comparison groups	Subjects who received Cervarix in a previous clinical trial. v Subjects who received Gardasil in a previous clinical trial
Number of subjects included in analysis	58
Analysis specification	Pre-specified
Analysis type	
P-value	< 5
Method	t-test, 2-sided

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Subjects were not monitored in terms of safety outcomes as the study consists of a single visit and one blood draw. No investigational medicinal products were given so it was not necessary to collect safety data or to report adverse events.

Assessment type	Non-systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	10

Reporting groups

Reporting group title	Study Cohort

Reporting group description: -

Serious adverse events	Study Cohort		
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 58 (0.00%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events	0		

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

Non-serious adverse events	Study Cohort		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	1 / 58 (1.72%)		
Skin and subcutaneous tissue disorders			
Acne			
subjects affected / exposed	1 / 58 (1.72%)		
occurrences (all)	1		

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