Clinical trial results:
Determination of the human papillomavirus (HPV)-specific antibody status in oral fluids of individuals vaccinated with a quadrivalent HPV vaccine

Summary

EudraCT number	2008-008605-22
Trial protocol	AT
Global end of trial date	01 June 2010

Results information

Result version number	v1 (current)
This version publication date	04 October 2019
First version publication date	04 October 2019

Trial information

Trial identification

Sponsor protocol code	1.0

Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	Medical University of Vienna
Sponsor organisation address	Waehringer Guertel 18-20, Vienna, Austria, 1090
Public contact	Prof Dr Reinhard Kirnbauer, Medical University of Vienna, +43 14040077680, reinhard.kirnbauer@meduniwien.ac.at
Scientific contact	Prof Dr Reinhard Kirnbauer, Medical University of Vienna, +43 14040077680, reinhard.kirnbauer@meduniwien.ac.at

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	25 June 2016
Is this the analysis of the primary completion data?	Yes
Primary completion date	01 May 2010
Global end of trial reached?	Yes
Global end of trial date	01 June 2010
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

Determination of the human papillomavirus (HPV)-specific antibody status in oral fluids of individuals vaccinated with the quadrivalent HPV vaccine Gardasil

Protection of trial subjects:

Anonymization

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	01 April 2009
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	Austria: 34
Worldwide total number of subjects	34
EEA total number of subjects	34

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:

female students

Pre-assignment

Screening details:

questionning of elegible participants: inclusion if less than 4 life-long sexual partners and no antecedent history of anogenital warts, anogenital dysplasia and cancer and abnormal PAP smear

Pre-assignment period milestones

Number of subjects started	34
Number of subjects completed	34

Period 1

Period 1 title	Recruitment (overall period)
Is this the baseline period?	Yes
Allocation method	Non-randomised - controlled
Blinding used	Not blinded

Blinding implementation details:

n.a.

Arms

Are arms mutually exclusive?	Yes
Arm title	vaccinees

Arm description: -

Arm type	Active comparator
Investigational medicinal product name	Gardasil
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Suspension for injection in pre-filled syringe
Routes of administration	Intramuscular use

Dosage and administration details:

0,5 ml in month 0, 2 and 6 intramuscular

Arm title	control

Arm description: -

Arm type	No intervention

No investigational medicinal product assigned in this arm

Number of subjects in period 1	vaccinees	control
Started	20	14
Completed	20	14

Baseline characteristics

Reporting groups

Reporting group title	Recruitment

Reporting group description: -

Reporting group values	Recruitment	Total	
Number of subjects	34	34	
Age categorical			
adults			
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)	34	34	
From 65-84 years	0	0	
85 years and over	0	0	
Age continuous			
adults			
Units: years			
arithmetic mean	23.2		
standard deviation	± 4	-	
Gender categorical			
Units: Subjects			
Female	34	34	
Male	0	0	

Subject analysis sets

Subject analysis set title	all participants
Subject analysis set type	Full analysis

Subject analysis set description:

OMT and blood samples of all participants

Reporting group values	all participants		
Number of subjects	34		
Age categorical			
adults			
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)	34		
From 65-84 years	0		
85 years and over	0		
Age continuous			
adults			
Units: years			
arithmetic mean	23.2		
standard deviation	± 4		
Gender categorical			
Units: Subjects			
Female	34		
Male	0		

End points

End points reporting groups	
Reporting group title	vaccinees
Reporting group description: -	
Reporting group title	control
Reporting group description: -	
Subject analysis set title	all participants
Subject analysis set type	Full analysis
Subject analysis set description: OMT and blood samples of all participants	

Primary: change in titers	
End point title	change in titers
End point description:	
End point type	Primary
End point timeframe: one month after final vaccination	

End point values	vaccinees	control		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	20	14		
Units: all participants	20	14		

Statistical analyses

Statistical analysis title	differences
Comparison groups	control v vaccinees
Number of subjects included in analysis	34
Analysis specification	Post-hoc
Analysis type	other
P-value	< 0.05
Method	Wilcoxon (Mann-Whitney)
Parameter estimate	Mean difference (final values)
Confidence interval	
level	95 %
sides	2-sided
Variability estimate	Standard deviation

Adverse events

Adverse events information	
Timeframe for reporting adverse events: 6 months	
Assessment type	Non-systematic

Dictionary used	
Dictionary name	MedDRA
Dictionary version	0

Reporting groups	
Reporting group title	all participants

Reporting group description: -

Serious adverse events	all participants		
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 34 (0.00%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events	0		

Frequency threshold for reporting non-serious adverse events: 1 %

Non-serious adverse events	all participants		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	3 / 34 (8.82%)		
Skin and subcutaneous tissue disorders			
Local reaction			
subjects affected / exposed	3 / 34 (8.82%)		
occurrences (all)	3		

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

Online references

http://www.ncbi.nlm.nih.gov/pubmed/26867163