



Clinical trial results:

A phase IV, single-blind, randomized, multicenter study to assess the immunogenicity and safety of GSK Biologicals' dTpa vaccine (Boostrix) using a new syringe presentation in healthy adolescents aged 10–15 years

Summary

EudraCT number	2013-003768-30
Trial protocol	Outside EU/EEA
Global end of trial date	03 September 2012

Results information

Result version number	v3 (current)
This version publication date	31 March 2023
First version publication date	13 May 2015
Version creation reason	• Correction of full data set Correction of full data set and alignment between registries.

Trial information

Trial identification

Sponsor protocol code	114778
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Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT01362322
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	GlaxoSmithKline Biologicals
Sponsor organisation address	Rue de l'Institut 89, Rixensart, Belgium,
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?	Yes

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	10 January 2014
Is this the analysis of the primary completion data?	Yes
Primary completion date	03 September 2012
Global end of trial reached?	Yes
Global end of trial date	03 September 2012
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To demonstrate that Boostrix administered using the new syringe presentation is non-inferior to Boostrix administered using the previous syringe presentation, in terms of immune response to all vaccine antigens, one month after booster vaccination.

Protection of trial subjects:

All subjects were supervised after vaccination/product administration with appropriate medical treatment readily available. Vaccines were administered by qualified and trained personnel. Vaccines were administered only to eligible subjects that had no contraindications to any components of the vaccines.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	05 July 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	Mexico: 376
Country: Number of subjects enrolled	Chile: 295
Worldwide total number of subjects	671
EEA total number of subjects	0

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)	671
Adolescents (12-17 years)	0
Adults (18-64 years)	0
From 65 to 84 years	0

85 years and over	0
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Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

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

Period 1

Period 1 title	Overall Study (overall period)
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Single blind
Roles blinded	Subject

Arms

Are arms mutually exclusive?	Yes
Arm title	Boostrix New Group

Arm description:

Subjects, aged 10 to 15 years, received one dose of Boostrix vaccine administered using a new syringe presentation (prefilled syringes from a different manufacturer) in the deltoid of the non-dominant arm, at Day 0.

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

Dosage and administration details:

One dose of vaccine, in a new syringe presentation, was administered in the deltoid of the non-dominant arm, at Day 0.

Arm title	Boostrix Prev Group
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Arm description:

Subjects, aged 10 to 15 years, received one dose of Boostrix vaccine administered using a previous syringe presentation (single dose vial or a prefilled disposable syringe without a needle) in the deltoid of the non-dominant arm, at Day 0.

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

Dosage and administration details:

One dose of vaccine, in a previous syringe presentation, was administered in the deltoid of the non-dominant arm, at Day 0.

Number of subjects in period 1	Boostrix New Group	Boostrix Prev Group
Started	335	336
Completed	330	329
Not completed	5	7
Consent withdrawn by subject	3	1
Lost to follow-up	2	6

Baseline characteristics

Reporting groups

Reporting group title	Boostrix New Group
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Reporting group description:

Subjects, aged 10 to 15 years, received one dose of Boostrix vaccine administered using a new syringe presentation (prefilled syringes from a different manufacturer) in the deltoid of the non-dominant arm, at Day 0.

Reporting group title	Boostrix Prev Group
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Reporting group description:

Subjects, aged 10 to 15 years, received one dose of Boostrix vaccine administered using a previous syringe presentation (single dose vial or a prefilled disposable syringe without a needle) in the deltoid of the non-dominant arm, at Day 0.

Reporting group values	Boostrix New Group	Boostrix Prev Group	Total
Number of subjects	335	336	671
Age categorical Units: Subjects			
In utero	0	0	0
Preterm newborn infants (gestational age < 37 wks)	0	0	0
Newborns (0-27 days)	0	0	0
Infants and toddlers (28 days-23 months)	0	0	0
Children (2-11 years)	335	336	671
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	0	0	0
From 65-84 years	0	0	0
85 years and over	0	0	0
Age continuous Units: years			
arithmetic mean	11.9	11.9	
standard deviation	± 1.59	± 1.61	-
Gender categorical Units: Subjects			
Female	179	178	357
Male	156	158	314

End points

End points reporting groups

Reporting group title	Boostrix New Group
Reporting group description: Subjects, aged 10 to 15 years, received one dose of Boostrix vaccine administered using a new syringe presentation (prefilled syringes from a different manufacturer) in the deltoid of the non-dominant arm, at Day 0.	
Reporting group title	Boostrix Prev Group
Reporting group description: Subjects, aged 10 to 15 years, received one dose of Boostrix vaccine administered using a previous syringe presentation (single dose vial or a prefilled disposable syringe without a needle) in the deltoid of the non-dominant arm, at Day 0.	

Primary: Anti-diphtheria (anti-D) and anti-tetanus (anti-T) antibody concentrations

End point title	Anti-diphtheria (anti-D) and anti-tetanus (anti-T) antibody concentrations
End point description: Concentrations are presented as geometric mean concentrations (GMCs), expressed in international units per milliliter (IU/mL).	
End point type	Primary
End point timeframe: At Month 1	

End point values	Boostrix New Group	Boostrix Prev Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	321	319		
Units: IU/mL				
geometric mean (confidence interval 95%)				
Anti-D	6.784 (6.178 to 7.45)	6.493 (5.915 to 7.128)		
Anti-T	18.937 (17.313 to 20.713)	18.515 (16.851 to 20.342)		

Statistical analyses

Statistical analysis title	Adjusted ratios of GMCs for anti-D
Statistical analysis description: Analysis was performed to demonstrate that the Boostrix vaccine administered using the new-syringe presentation was non-inferior to Boostrix vaccine administered using the previous-syringe, in terms of immune response to diphtheria vaccine antigens, one month after booster vaccination.	
Comparison groups	Boostrix New Group v Boostrix Prev Group

Number of subjects included in analysis	640
Analysis specification	Pre-specified
Analysis type	non-inferiority ^[1]
Method	ANCOVA
Parameter estimate	Adjusted Ratio
Point estimate	0.96
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.85
upper limit	1.09

Notes:

[1] - The upper limit (UL) of the 95% confidence interval (CI) on the geometric mean concentration (GMC) ratios [Boostrix-Prev Group over Boostrix-New Group] for anti-diphtheria (anti-D) antibodies was lesser than or equal to ($\leq$) 1.5 (clinical limit for non-inferiority).

Statistical analysis title	Adjusted ratios of GMCs for anti-T
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Statistical analysis description:

Analysis was performed to demonstrate that the Boostrix vaccine administered using the new-syringe presentation was non-inferior to Boostrix vaccine administered using the previous-syringe, in terms of immune response to tetanus vaccine antigens, one month after booster vaccination.

Comparison groups	Boostrix New Group v Boostrix Prev Group
Number of subjects included in analysis	640
Analysis specification	Pre-specified
Analysis type	non-inferiority ^[2]
Method	ANCOVA
Parameter estimate	Adjusted Ratio
Point estimate	0.97
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.86
upper limit	1.1

Notes:

[2] - The upper limit (UL) of the 95% confidence interval (CI) on the geometric mean concentration (GMC) ratios [Boostrix-Prev Group over Boostrix-New Group] for anti-tetanus (anti-T) antibodies was $\leq$ 1.5 (clinical limit for non-inferiority).

Primary: Anti-pertussis toxoid (anti-PT), anti-filamentous haemagglutinin (anti-FHA), anti-pertactin (anti-PRN) antibody concentrations

End point title	Anti-pertussis toxoid (anti-PT), anti-filamentous haemagglutinin (anti-FHA), anti-pertactin (anti-PRN) antibody concentrations
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End point description:

Concentrations are presented as geometric mean concentrations (GMCs), expressed in enzyme-linked immunosorbent assay (ELISA) units per milliliter (EL.U/mL).

End point type	Primary
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End point timeframe:

At Month 1

End point values	Boostrix New Group	Boostrix Prev Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	321	319		
Units: EU/mL				
geometric mean (confidence interval 95%)				
Anti-PT [N=318;318]	140.2 (126 to 156.1)	125.9 (112.7 to 140.7)		
Anti-FHA [N=319;319]	1080.2 (995.2 to 1172.5)	1013.7 (940 to 1093.2)		
Anti-PRN [N=321;318]	652.4 (572.1 to 743.9)	619.2 (546 to 702.2)		

Statistical analyses

Statistical analysis title	Adjusted ratios of GMCs for anti-PT
Statistical analysis description:	
Analysis was performed to demonstrate that the Boostrix vaccine administered using the new-syringe presentation was non-inferior to Boostrix vaccine administered using the previous-syringe, in terms of immune response to pertussis toxoid vaccine antigens, one month after booster vaccination.	
Comparison groups	Boostrix New Group v Boostrix Prev Group
Number of subjects included in analysis	640
Analysis specification	Pre-specified
Analysis type	non-inferiority ^[3]
Method	ANCOVA
Parameter estimate	Adjusted Ratio
Point estimate	0.92
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.82
upper limit	1.04

Notes:

[3] - The upper limit (UL) of the 95% confidence interval (CI) on the geometric mean concentration (GMC) ratios [Boostrix-Prev Group over Boostrix-New Group] for anti-pertussis toxoid (anti-PT) antibodies was ≤ 1.5 (clinical limit for non-inferiority).

Statistical analysis title	Adjusted ratios of GMCs for anti-FHA
Statistical analysis description:	
Analysis was performed to demonstrate that the Boostrix vaccine administered using the new-syringe presentation was non-inferior to Boostrix vaccine administered using the previous-syringe, in terms of immune response to filamentous haemagglutinin vaccine antigens, one month after booster vaccination.	
Comparison groups	Boostrix New Group v Boostrix Prev Group
Number of subjects included in analysis	640
Analysis specification	Pre-specified
Analysis type	non-inferiority ^[4]
Method	ANCOVA
Parameter estimate	Adjusted Ratio
Point estimate	0.92

Confidence interval	
level	95 %
sides	2-sided
lower limit	0.83
upper limit	1.03

Notes:

[4] - The upper limit (UL) of the 95% confidence interval (CI) on the geometric mean concentration (GMC) ratios [Boostrix-Prev Group over Boostrix-New Group] for anti-filamentous haemagglutinin (anti-FHA) antibodies was ≤ 1.5 (clinical limit for non-inferiority).

Statistical analysis title	Adjusted ratios of GMCs for anti-PRN
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Statistical analysis description:

Analysis was performed to demonstrate that the Boostrix vaccine administered using the new-syringe presentation was non-inferior to Boostrix vaccine administered using the previous-syringe, in terms of immune response to pertactin vaccine antigens, one month after booster vaccination.

Comparison groups	Boostrix New Group v Boostrix Prev Group
Number of subjects included in analysis	640
Analysis specification	Pre-specified
Analysis type	non-inferiority ^[5]
Method	ANCOVA
Parameter estimate	Adjusted Ratio
Point estimate	0.98
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.85
upper limit	1.13

Notes:

[5] - The upper limit (UL) of the 95% confidence interval (CI) on the geometric mean concentration (GMC) ratios [Boostrix-Prev Group over Boostrix-New Group] for anti-pertactin (anti-PRN) antibodies was ≤ 1.5 (clinical limit for non-inferiority).

Primary: Anti-diphtheria (anti-D) and anti-tetanus (anti-T) antibody concentrations

End point title	Anti-diphtheria (anti-D) and anti-tetanus (anti-T) antibody concentrations ^[6]
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End point description:

Concentrations are presented as geometric mean concentrations (GMCs), expressed in international units per milliliter (IU/mL).

End point type	Primary
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End point timeframe:

At Day 0

Notes:

[6] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: The analysis of the primary endpoint was descriptive i.e. no statistical hypothesis test was performed.

End point values	Boostrix New Group	Boostrix Prev Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	321	319		
Units: IU/mL				
geometric mean (confidence interval 95%)				
Anti-D	0.472 (0.403 to 0.553)	0.456 (0.392 to 0.53)		

Anti-T	0.956 (0.835 to 1.095)	0.899 (0.789 to 1.026)		
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Statistical analyses

No statistical analyses for this end point

Primary: Anti-pertussis toxoid (anti-PT), anti-filamentous haemagglutinin (anti-FHA), anti-pertactin (anti-PRN) antibody concentrations

End point title	Anti-pertussis toxoid (anti-PT), anti-filamentous haemagglutinin (anti-FHA), anti-pertactin (anti-PRN) antibody concentrations ^[7]
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End point description:

Concentrations are presented as geometric mean concentrations (GMCs), expressed in ELISA units per milliliter (EL.U/mL).

End point type	Primary
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End point timeframe:

At Day 0

Notes:

[7] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: The analysis of the primary endpoint was descriptive i.e. no statistical hypothesis test was performed.

End point values	Boostrix New Group	Boostrix Prev Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	320	319		
Units: EL.U/mL				
geometric mean (confidence interval 95%)				
Anti-PT PRE [N=320;319]	7.5 (6.6 to 8.7)	7.2 (6.3 to 8.2)		
Anti-FHA PRE [N=316;315]	48.9 (43.3 to 55.2)	49.4 (43.6 to 56)		
Anti-PRN PRE [N=321;319]	14 (12.3 to 15.9)	13.4 (11.9 to 15)		

Statistical analyses

No statistical analyses for this end point

Secondary: Number of seropositive subjects against Diphtheria(D) and Tetanus(T) antigens

End point title	Number of seropositive subjects against Diphtheria(D) and Tetanus(T) antigens
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End point description:

A seroprotected subject was defined as a subject whose antibody concentration was greater than or equal to ($\geq$) 0.1. international units per milliliter (IU/mL), as assessed by the Enzyme Linked Immunosorbent Assay (ELISA).

End point type	Secondary
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End point timeframe:

At Day 0 (PRE) and at Month 1 (POST)

End point values	Boostrix New Group	Boostrix Prev Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	321	319		
Units: subjects				
Anti-D PRE	284	286		
Anti-D POST	320	319		
Anti-T PRE	311	314		
Anti-T POST	321	319		

Statistical analyses

No statistical analyses for this end point

Secondary: Number of seroprotected subjects against Diphtheria(D) and Tetanus(T) antigens

End point title	Number of seroprotected subjects against Diphtheria(D) and Tetanus(T) antigens
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End point description:

A seroprotected subject is defined as a vaccinated subject with anti-D and anti-T antibody concentration greater than or equal to ($\geq$) 1 international units per milliliter (IU/mL).

End point type	Secondary
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End point timeframe:

At Day 0 (PRE) vaccine and at Month 1 (POST)

End point values	Boostrix New Group	Boostrix Prev Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	321	319		
Units: subjects				
Anti-D PRE	83	89		
Anti-D POST	315	310		
Anti-T PRE	151	143		
Anti-T POST	321	319		

Statistical analyses

No statistical analyses for this end point

Secondary: Number of seropositive subjects with anti-pertussis toxoid (anti-PT), anti-filamentous haemagglutinin (anti-FHA) and anti-pertactin (anti-PRN) antibody concentrations

End point title	Number of seropositive subjects with anti-pertussis toxoid (anti-PT), anti-filamentous haemagglutinin (anti-FHA) and anti-pertactin (anti-PRN) antibody concentrations
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End point description:

A seroprotected subject was defined as a subject whose antibody concentration was greater than or equal to ($\geq$) 5 Enzyme Linked Immunosorbent Assay (ELISA) units per milliliter (EL.U/mL).

End point type	Secondary
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End point timeframe:

At Day 0 (PRE) vaccine and at Month 1 (POST)

End point values	Boostrix New Group	Boostrix Prev Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	321	319		
Units: subjects				
Anti-PT PRE [N=320;319]	175	175		
Anti-PT POST [N=318;318]	316	315		
Anti-FHA PRE [N=316;315]	310	310		
Anti-FHA POST [N=319;319]	319	319		
Anti-PRN PRE [N=321;319]	269	272		
Anti-PRN POST [N=321;318]	321	318		

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with booster response to diphtheria (D) and tetanus (T) antibodies

End point title	Number of subjects with booster response to diphtheria (D) and tetanus (T) antibodies
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End point description:

Booster response to the diphtheria and tetanus antigens, was defined as: for initially seronegative subjects (pre-vaccination concentration <0.1 IU/mL): antibody concentrations at least 4 times the cut-off (post-vaccination concentration ≥ 0.4 IU/mL); for initially seropositive subjects (pre-vaccination concentration ≥ 0.1 IU/mL): an increase in antibody concentrations of at least 4 times the pre-vaccination concentration.

End point type	Secondary
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End point timeframe:

At Month 1

End point values	Boostrix New Group	Boostrix Prev Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	321	319		
Units: subjects				
Anti-D	257	252		
Anti-T	266	270		

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with a booster response to PT, FHA and PRN antibodies

End point title	Number of subjects with a booster response to PT, FHA and PRN antibodies
End point description: Booster response to the PT, FHA and PRN antigens, was defined as: for initially seronegative subjects: antibody concentrations at least 4 times the cut-off (post-vaccination concentration $\geq$ 20 EL.U/mL); for initially seropositive subjects with pre-vaccination concentration $\geq$ 5 EL.U/mL and $<$ 20 EL.U/mL: an increase in antibody concentrations of at least 4 times the pre-vaccination concentration; and for initially seropositive subjects with pre-vaccination concentration $\geq$ 20 EL.U/mL: an increase in antibody concentrations of at least 2 times the pre-vaccination concentration.	
End point type	Secondary
End point timeframe: At Month 1	

End point values	Boostrix New Group	Boostrix Prev Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	321	318		
Units: subjects				
Anti-PT [N=317;318]	298	295		
Anti-FHA [N=314;315]	305	304		
Anti-PRN [N=321;318]	315	317		

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with any solicited local symptoms

End point title	Number of subjects with any solicited local symptoms
End point description: Assessed solicited local symptoms were pain, redness and swelling. Any = occurrence of the symptom regardless of intensity grade.	
End point type	Secondary

End point timeframe:

Within 4 days (Days 0-3) post vaccination period

End point values	Boostrix New Group	Boostrix Prev Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	330	329		
Units: subjects				
Any Pain	237	248		
Any Redness	113	94		
Any Swelling	98	90		

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with any solicited general symptoms

End point title	Number of subjects with any solicited general symptoms
End point description: Assessed solicited general symptoms were fatigue, temperature [defined as axillary temperature equal to or above 37.5 degrees Celsius (°C)], headache and gastrointestinal symptoms. Gastrointestinal symptoms included Nausea, Vomiting, Diarrhea and or Abdominal pain. Any = occurrence of the symptom regardless of intensity grade.	
End point type	Secondary
End point timeframe: Within 4 days (Days 0-3) post vaccination period	

End point values	Boostrix New Group	Boostrix Prev Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	330	329		
Units: subjects				
Any Fatigue	83	86		
Any Gastrointestinal symptoms	32	42		
Any Headache	88	108		
Any Temperature	9	6		

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with unsolicited adverse events (AEs)

End point title	Number of subjects with unsolicited adverse events (AEs)
End point description:	
An unsolicited AE covers any untoward medical occurrence in a clinical investigation subject temporally associated with the use of a medicinal product, whether or not considered related to the medicinal product and reported in addition to those solicited during the clinical study and any solicited symptom with onset outside the specified period of follow-up for solicited symptoms. Any was defined as the occurrence of any unsolicited AE regardless of intensity grade or relation to vaccination.	
End point type	Secondary
End point timeframe:	
Within 31 days (Days 0-30) post vaccination period	

End point values	Boostrix New Group	Boostrix Prev Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	335	336		
Units: subjects				
Any unsolicited AEs	44	45		

Statistical analyses

No statistical analyses for this end point

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

End point title	Number of subjects with serious adverse events (SAEs)
End point description:	
Serious adverse events (SAEs) assessed include medical occurrences that result in death, are life threatening, require hospitalization or prolongation of hospitalization or result in disability/incapacity.	
End point type	Secondary
End point timeframe:	
During the entire study period (Day 0 - Month 1)	

End point values	Boostrix New Group	Boostrix Prev Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	335	336		
Units: subjects				
Any SAEs	1	0		

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Solicited symptoms during the 4-day post-vaccination period (Day 0 - Day 3), Unsolicited AEs during the 31-day post-vaccination period (Day 0 - Day 30), SAEs during the entire period (Day 0 - Month 1).

Assessment type	Systematic
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Dictionary used

Dictionary name	MedDRA
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Dictionary version	16.1
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Reporting groups

Reporting group title	Boostrix Prev Group
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Reporting group description:

Subjects, aged 10 to 15 years, received one dose of Boostrix vaccine administered using a previous syringe presentation (single dose vial or a prefilled disposable syringe without a needle) in the deltoid of the non-dominant arm, at Day 0.

Reporting group title	Boostrix New Group
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Reporting group description:

Subjects, aged 10 to 15 years, received one dose of Boostrix vaccine administered using a new syringe presentation (prefilled syringes from a different manufacturer) in the deltoid of the non-dominant arm, at Day 0.

Serious adverse events	Boostrix Prev Group	Boostrix New Group	
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 336 (0.00%)	1 / 335 (0.30%)	
number of deaths (all causes)	0	0	
number of deaths resulting from adverse events			
Injury, poisoning and procedural complications			
Injury			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 336 (0.00%)	1 / 335 (0.30%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	

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

Non-serious adverse events	Boostrix Prev Group	Boostrix New Group	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	279 / 336 (83.04%)	263 / 335 (78.51%)	
General disorders and administration site conditions			

Pain		
subjects affected / exposed	248 / 336 (73.81%)	237 / 335 (70.75%)
occurrences (all)	248	237
Redness		
subjects affected / exposed	94 / 336 (27.98%)	113 / 335 (33.73%)
occurrences (all)	94	113
Swelling		
subjects affected / exposed	90 / 336 (26.79%)	98 / 335 (29.25%)
occurrences (all)	90	98
Fatigue		
subjects affected / exposed	86 / 336 (25.60%)	83 / 335 (24.78%)
occurrences (all)	86	83
Gastrointestinal symptoms		
subjects affected / exposed	42 / 336 (12.50%)	32 / 335 (9.55%)
occurrences (all)	42	32
Headache		
subjects affected / exposed	109 / 336 (32.44%)	89 / 335 (26.57%)
occurrences (all)	110	90

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
29 May 2012	At the European Medicines Agency's (EMA) request, GSK Biologicals has updated its procedure for emergency unblinding during the conduct of a clinical study. According to the revised procedure, the responsibility and the decision to break the treatment code in emergency situations resides solely with the investigator and consequently, the investigator will have full authority to break the treatment code. The Emergency unblinding is not applicable for open and single blind studies anymore. Therefore the section has been deleted.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported